EXHIBIT 7

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The present invention relates to a medication delivery device having a cartridge and a dosing assembly coupled together for delivering selected doses of medication, wherein at least one of the coupling means of the cartridge is unitarily moulded with the cartridge.

Background

Some medication, such as insulin is self-administered. The typical diabetes patient will require injections of insulin several times during the day. The required insulin dose will vary from patient to patient, and will for each patient often also vary during the day. Each patient will often establish a regimen for the insulin administration adjusted to his or her insulin need as well as lifestyle. Medication delivery pens have been developed to facilitate the self-administration of medication, such as insulin.

One prior art medication delivery pen includes a pen body assembly comprising a medication cartridge and a plunger device. A needle assembly may be connected to the pen body assembly. The medication is delivered by moving or pressing a plunger in the direction of the needle assembly thereby delivering the medication. When the medication in the cartridge is exhausted the pen body assembly is discarded. Depending on the medication needs for each individual the medication in the cartridge will last for several days. During this period the needle assembly will often have to be displaced by a new assembly or new needle due to increasing bluntness of the needle making injections painful for the patient.

More recent developments have revealed medication delivery pens, wherein the cartridge holder assembly can be disassembled from the pen body assembly after the medication therein has been exhausted, discarded and replaced by a new medicine-containing cartridge assembly.

An example of this is shown in EP 0 666 571 disclosing a medication delivery pen having a reusable pen body assembly and a disposable cartridge assembly that are threadedly engageable with one another. The cartridge assembly comprises a cartridge, a cartridge housing, a cap between the distal end of the cartridge and the housing, securing the cartridge in the housing and being adapted for engagement

with a needle assembly. Furthermore, the cartridge comprises a plunger within the cartridge. The reusable pen body assembly is coupled through a threaded coupling to the cartridge housing. Thus, the total number of parts comprising the prior art cartridge assembly is high.

It is an object of the present invention to provide a medication delivery device wherein the amount of parts of the cartridge is minimised.

Summary of the invention

Accordingly, the present invention relates to a medication delivery device comprising a cartridge assembly, a dosing assembly and optionally a needle assembly,

said cartridge assembly having one end sealed with a pierceable sealing, said end of the cartridge assembly comprising coupling means for engaging a needle assembly, and another end comprising coupling means for engaging the dosing assembly, said cartridge assembly further comprising a cartridge wherein at least one of the coupling means of said cartridge assembly is unitarily moulded with the cartridge, the cartridge further comprising a stopper adapted to receive plunger means, and

said dosing assembly comprising plunger means has coupling means for engaging the cartridge assembly, and said plunger means is adapted to engage the stopper of the cartridge when the dosing assembly is coupled to the cartridge.

The above-described medication delivery device has fewer parts that the prior art devices because at least one coupling means is moulded unitarily with the cartridge. Thereby the costs involved in the production and assembling of the device are reduced, and the device is more economical, which is an important feature for a disposable device.

The medical delivering device may either be manufactured as a disposable device which is sold pre-filled with the insulin or it may appear as a durable medical delivering device so designed that it can receive disposable cartridges with insulin.

In a preferred embodiment the dosing assembly is reusable and the cartridge assembly is disposable, and accordingly, a second aspect of the present invention is a medication delivery device wherein the dosing assembly is releasably coupled to the cartridge assembly.

The medication delivery device is preferably constructed as to secure that the plunger means abuts on the stopper during use of the device, such as attaching and releasing the needle assembly. It is understood that the plunger means must disengage the stopper when the cartridge assembly is deliberately released from a reusable dosing assembly because the medication in the cartridge has been exhausted and the cartridge assembly is to be discarded. In this situation the plunger means is to be retracted to the dosing assembly before assembling the device with a new cartridge assembly.

Securing the abutment of the plunger means on the stopper during use of the medication delivery device, in particular when the needle assembly is coupled to and/or decoupled from the cartridge assembly, may be carried out by a variety of means. In a preferred embodiment the abutment is secured by preventing the cartridge assembly from being inadvertently released from the dosing assembly.

In particular, when the cartridge assembly is released from the dosing assembly through a movement including an axial movement, such as through a threaded coupling, it is preferred that the means for releasably coupling the needle assembly and the cartridge assembly together are such that the coupling and/or decoupling of the needle assembly cannot cause an axial movement of the cartridge assembly with respect to the dosing assembly. Thus, in that respect examples of the preferred couplings between the needle assembly and the cartridge assembly include releasable snap locks. Another preferred embodiment includes a safety on the coupling between the dosing assembly and the cartridge assembly, such as hinge on the coupling or a threaded coupling releasable only after exerting an axial pressure on the coupling.

A second aspect of the present invention is a cartridge assembly for use in a medication delivery device, said cartridge assembly having one end sealed with a pierceable sealing, said end of the cartridge assembly comprising coupling means for engaging a needle assembly, and another end comprising coupling means for engaging the dosing assembly, said cartridge assembly further comprising a cartridge wherein at least one of the coupling means of said cartridge assembly is unitarily moulded with the cartridge, said cartridge further comprising a stopper.

The cartridge assembly may further comprise a cartridge housing for protecting the cartridge in use. Furthermore, when the cartridge is moulded unitarily with one coupling means the cartridge housing may comprise the other coupling means. Accordingly, in one embodiment of the invention the housing of the cartridge assembly comprises coupling means for coupling the cartridge assembly to the dosing assembly, preferably the coupling means is moulded unitarily with the housing. The cartridge is arranged within the cartridge housing. The cartridge housing may be non-releasably attached to the cartridge, once the cartridge is arranged in the housing, whereby the housing is disposed with the cartridge. In another embodiment the housing is reusable and the cartridge is arranged releasably in the housing.

In a preferred embodiment all the coupling means of the cartridge assembly are unitarily moulded with the cartridge. Thereby, it is possible to construct the cartridge assembly without the housing providing a cartridge assembly with even fewer parts.

The coupling means of the cartridge assembly may be for any suitable coupling, preferably a releasable coupling. Examples of the coupling are snap locks, such as snap locks with guidewire and sideways snap locks, snap locks released through threads, bajonet locks, luer locks, hinged locks, threaded locks and any suitable combinations thereof.

The coupling means unitarily moulded with the cartridge are preferably external coupling means, such as an external threaded coupling.

The cartridge may be moulded from any material suitable for medical containers. The cartridge is preferably moulded from a plastic material, e.g. by injection moulding. A suitable choice of material allows the cartridge to be at least partly transpar-

ent, whereby the user can see whether liquid is left in the cartridge. In a preferred embodiment the cartridge is totally transparent giving the user a greater possibility of inspecting the content of the cartridge.

By using a plastic material as compared to the usual glass material a great advantage is achieved in the production lines. Normally a significant quantity of the produced glass cartridges will be spoiled in the lines due to breakage, however the loss is greatly reduced by the use of plastic cartridges. Furthermore, the risk of small loose glass particles in the cartridges have been eliminated.

The cartridge may be of any suitable form, such as a cylinder. The cylinder may be constructed with various combinations of circular or non-circular inner and outer cross-section. In another embodiment the cartridge may be box-shaped having essentially rectangular or triangular cross-section.

The stopper is in sliding fluid tight engagement in the cartridge. The stopper is preferably made of plastic and/or rubber material.

The flexibility of the cartridge wall is not critical, however if the cartridge is too flexible the function of the stopper may be impaired. Mostly, the cartridge is made of a material only slightly flexible to non-flexible.

In order to enforce and strengthen the cartridge wall the cartridge may be integrally moulded with reinforcements. Thereby, the necessity of a protective housing may be obviated. Furthermore, a scale may be integrally moulded with the cartridge wall providing the user with a measure for the medication used and left.

In a most preferred embodiment the cartridge assembly is comprised only of a cartridge being sealed in one end with a sealing, being unitarily moulded with all couplings means and comprising a stopper.

In a cylindrical cartridge the two couplings of the cartridge assembly are generally opposing each other. However, the coupling for engaging with the dosing assembly being separate from coupling for engaging the needle assembly may be arranged in any angle with respect to the latter coupling.

Another aspect of the present invention is a cartridge being at least partly filled with liquid medication, such as insulin.

Drawings

Fig. 1 is an exploded perspective view of the medication delivery device.

Fig. 2 is a cross-sectional view showing part of the medication delivery device, 2a immediately after assembling before the first injection, and 2b after some time of use.

Fig. 3 is a cross-sectional view showing the cartridge before assembling of the medication delivery device.

Detailed description of the invention

A medication delivery device in accordance with the present invention is identified generally by the numeral 20 in Fig. 1 and 2. Medication delivery device 20 includes a dosing assembly 6, and cartridge assembly 1, a needle assembly 18 and a cap 14.

The dosing assembly 6 is illustrated in Fig. 1 and 2. It is understood, however, that the dosing assembly 6 according to the invention may be any suitable dosing unit including plunger means, and accordingly, that variations from the depicted embodiment may be provided, and are considered to be within the scope of this invention. In the depicted embodiment the dosing assembly 6 includes a cylindrical housing surrounding the plunger means 17 of the dosing unit and having opposed proximal and distal ends.

In one aspect of the invention the plunger means comprises a rod element 7 which is adapted to engage the stopper 4 of the cartridge assembly 1. The rod element 7 advances axially into the cartridge 5 during injections. The dosing assembly may have any suitable driving means for advancing the rod element 7.

The dosing unit 6 preferably also comprises scale means 10 indicating the dosing quantity selected by activating the dose setting means 9 for defining specified selected doses of medication to be delivered. The selected dose may be delivered by actuating the actuator button 18. The actuator button is part of the driving means of the dosing assembly exerting its force on the rod element 7.

The dosing assembly further comprises coupling means 8 adapted for engagement with the cartridge assembly. The coupling means 8 may be internal or external couplings. In a preferred embodiment the coupling 8 is an internal coupling.

The cartridge assembly 1 is illustrated in Fig. 1 and 2, and in greater detail in Fig. 3. In Fig. 1 cartridge assembly 1 includes a moulded cartridge 5 extending from proximal end 21 to distal end 22.

At the distal end 22 of the cartridge assembly 1 is provided coupling means 2 for releasably mounting a needle assembly 11. At the proximal end 21 of the cartridge assembly 1 is provided coupling means 3 for mounting a dosing assembly 6. The coupling means are as described above.

Cartridge 5 also comprises a stopper 4 in sliding fluid tight engagement within said cartridge 5. The stopper 4 is adapted to receive the plunger means, such as a rod element 7 of the dosing assembly 6. The rod element 7 is adapted to exert an axial movement of the stopper 4 towards the sealed end 22 of the cartridge 5.

The cartridge assembly 1 may further comprise a housing for protecting some or all of the cartridge 5. When the cartridge assembly 1 includes a housing, one of the couplings 2, 3 of the cartridge may be moulded unitarily with the housing.

Instead of the protective housing the cartridge 5 may have integrally moulded reinforcements of the cartridge wall.

The depicted cartridge 5 is cylindrical having couplings 2, 3 at opposed ends. However, the cartridge may obtain any suitable form and the cross-section may be circular or non-circular, such as substantially triangular or oval.

The device according to the invention may include a protective cap 14 that is removably mounted over the cartridge assembly 1 and/or the needle 11 and which is removed before injection of the medication in the cartridge 5. The cap further ensures that the content of the cartridge is protected against sunlight.

Referring to Fig. 3 the coupling means of the cartridge are shown in greater detail. The coupling means 3 is an external thread, whereas the coupling means 2 is a recess for a snap lock of the needle assembly. Both coupling means are moulded unitarily with the cartridge.

The various parts of the medication delivery device are advantageously made of plastics, e.g. by injection moulding.

The medication delivery device 20 may further comprise any appropriate needle assembly 11, such as a double ended needle 13 having opposed proximal and distal points and a lumen extending axially therebetween.

A mounting hub 12 is engaged on the needle 13 and is removably connected to the coupling means 2 at the needle end of the cartridge assembly. The relative location of the mounting hub 12 ensures that the proximal point of the needle 13 will pierce the sealing when the mounting hub 12 is engaged with the coupling means 2 on the cartridge assembly 1.

The needle assembly 11 may further comprise a removable shield or cap 15 for protecting against accidental needle sticks.

The device according to the invention is suitable for delivering pre-set dosages of insulin, it is however understood that the device is suitable for the injection of pre-set dosages of other liquids.

In use the user will set the dose by means of the dose setting means 9. Before activating the actuator button 18 the cap 14 must be removed from the cartridge assembly 1 whereby the device 20 is prepared for an injection. The injection is effected by activating the actuator button 18, which again will effect the stopper 4 to be moved towards the sealed end 22 of the cartridge 5, thereby delivering the desi-

rod pre-set dosage. A subsequent dosage of medication will be set in exactly the same manner as described above. However, for such a subsequent dosage, the rod element 7 and the stopper 4 will be in a partly advanced position as starting point. Dose setting and injections can be carried out until all of the medication has been used.

Claims:

1. A medication delivery device comprising a cartridge assembly, a dosing assembly and optionally a needle assembly,

said cartridge assembly having one end sealed with a pierceable sealing, said end of the cartridge assembly comprising coupling means for engaging a needle assembly, and another end comprising coupling means for engaging the dosing assembly, said cartridge assembly further comprising a cartridge wherein at least one of the coupling means of said cartridge assembly is unitarily moulded with the cartridge, the cartridge further comprising a stopper adapted to receive plunger means, and

said dosing assembly comprising plunger means having coupling means for engaging the cartridge, and said plunger means is adapted to engage the stopper of the cartridge when the dosing assembly is coupled to the cartridge.

2. A medication delivery device according to claim 1, wherein all the coupling means of the cartridge assembly are unitarily moulded with the cartridge.

3. A medication delivery device according to claim 1 or 2, wherein at least one coupling means of the cartridge is an external coupling.

4. A medication delivery device according to any of the preceding claims, wherein at least one coupling means of the cartridge is a threaded coupling.

5. A medication delivery device according to any of the preceding claims, wherein the cartridge is moulded of a plastic material.

6. A medication delivery device according to any of the preceding claims, wherein the cartridge is at least partly transparent.

7. A medication delivery device according to any of the preceding claims, wherein reinforcements of the cartridge wall are integrally moulded with the cartridge.

8. A medication delivery device according to any of the preceding claims, wherein the cartridge further comprises a cartridge housing.

9. A medication delivery device according to any of the preceding claims, wherein the cartridge further comprise a scale.

10. A medication delivery device according to any of the preceding claims, wherein the cross-section of the cartridge is non-circular.

11. A medication delivery device according to any of the preceding claims, wherein the coupling means of the cartridge are opposed each other.

12. A cartridge assembly for use in a medication delivery device, said cartridge assembly having one end sealed with a pierceable sealing, said end of the cartridge assembly comprising coupling means for engaging a needle assembly, and another end comprising coupling means for engaging the dosing assembly, said cartridge assembly further comprising a cartridge wherein at least one of the coupling means of said cartridge assembly is unitarily moulded with the cartridge, said cartridge further comprising a stopper.

13. A cartridge assembly according to claim 12, wherein all the coupling means of the cartridge are unitarily moulded with the cartridge.

14. A cartridge assembly according to claim 12 or 13, wherein at least one coupling means of the cartridge is an external coupling.

15. A cartridge assembly according to any of the claims 12-14, wherein at least one coupling means of the cartridge is a threaded coupling.

16. A cartridge assembly according to any of the claims 12-15, wherein the cartridge is moulded of a plastic material.

17. A cartridge assembly according to any of the preceding 12-16, wherein the cartridge is at least partly transparent.

18. A cartridge assembly according to any of the claims 12-17, wherein reinforcements of the cartridge wall are integrally moulded with the cartridge.

19. A cartridge assembly according to any of the claims 12-18, wherein the cartridge further comprises a cartridge housing.

20. A cartridge assembly according to any of the claims 12-19, wherein the cartridge further comprise a scale.

21. A cartridge assembly according to any of the claims 12-20, wherein the cross-section of the cartridge is non-circular.

22. A cartridge assembly according to any of the claims 12-21, wherein the coupling means of the cartridge are opposed each other.

23. A cartridge assembly according to any of the claims 12-22, which is filled with medicine.

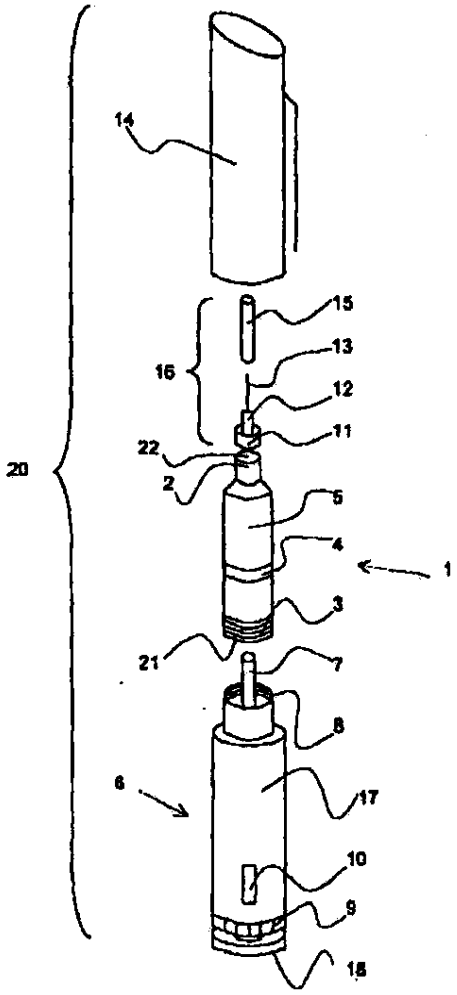

Fig. 1

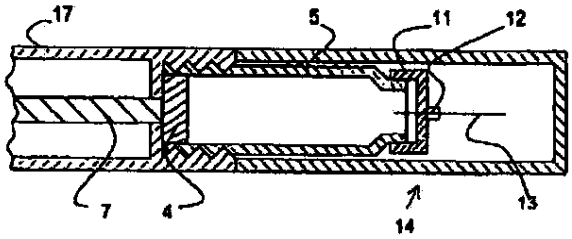

Fig. 2 a

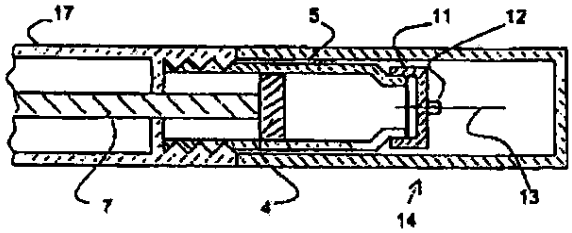

Fig. 2 b

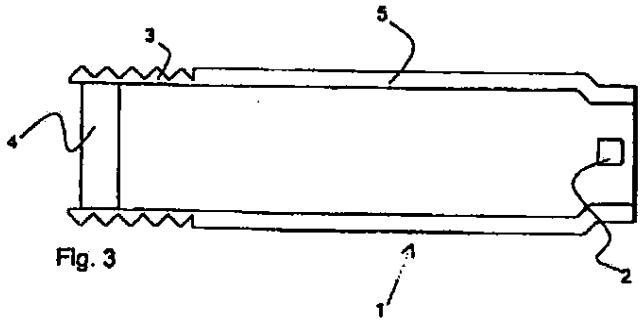

Fig. 3

EXHIBIT 8

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Class	Subclass	ISSUE CLASSIFICATION

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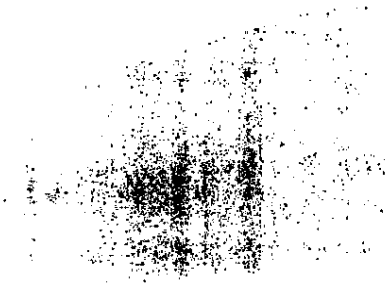

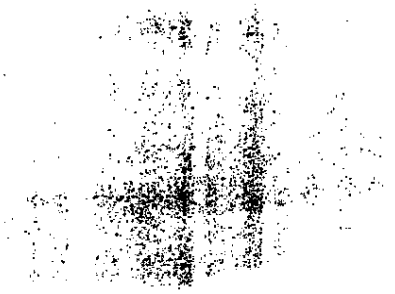

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SCAN 11

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PATENT APPLICATION

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Application papers.

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3. Request for access [illegible]

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PATENT APPLICATION SERIAL NO. _____

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE
FEE RECORD SHEET

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ABSTRACT IS MISSING IN THE FILE.

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The present invention relates to a medication delivery device having a cartridge and a dosing assembly coupled together for delivering selected doses of medication, wherein at least one of the coupling means of the cartridge is unitarily moulded with the cartridge.

Background

Some medication, such as insulin is self-administered. The typical diabetes patient will require injections of insulin several times during the day. The required insulin dose will vary from patient to patient, and will for each patient often also vary during the day. Each patient will often establish a regimen for the insulin administration adjusted to his or her insulin need as well as lifestyle. Medication delivery pens have been developed to facilitate the self-administration of medication, such as insulin.

One prior art medication delivery pen includes a pen body assembly comprising a medication cartridge and a plunger device. A needle assembly may be connected to the pen body assembly. The medication is delivered by moving or pressing a plunger in the direction of the needle assembly thereby delivering the medication. When the medication in the cartridge is exhausted the pen body assembly is discarded. Depending on the medication needs for each individual the medication in the cartridge will last for several days. During this period the needle assembly will often have to be displaced by a new assembly or new needle due to increasing bluntness of the needle making injections painful for the patient.

More recent developments have revealed medication delivery pens, wherein the cartridge holder assembly can be disassembled from the pen body assembly after the medication therein has been exhausted, discarded and replaced by a new medicine-containing cartridge assembly.

An example of this is shown in EP 0 688 571 disclosing a medication delivery pen having a reusable pen body assembly and a disposable cartridge assembly that are threadedly engageable with one another. The cartridge assembly comprises a cartridge, a cartridge housing, a cap between the distal end of the cartridge and the housing, securing the cartridge in the housing and being adapted for engagement

with a needle assembly. Furthermore, the cartridge comprises a plunger within the cartridge. The reusable pen body assembly is coupled through a threaded coupling to the cartridge housing. Thus, the total number of parts comprising the prior art cartridge assembly is high.

It is an object of the present invention to provide a medicalton delivery device wherein the amount of parts of the cartridge is minimised.

Summary of the invention

Accordingly, the present invention relates to a medication delivery device comprising a cartridge assembly, a dosing assembly and optionally a needle assembly,

said cartridge assembly having one end sealed with a pierceable sealing, said end of the cartridge assembly comprising coupling means for engaging a needle assembly, and another end comprising coupling means for engaging the dosing assembly, said cartridge assembly further comprising a cartridge wherein at least one of the coupling means of said cartridge assembly is unitarily moulded with the cartridge, the cartridge further comprising a stopper adapted to receive plunger means, and

said dosing assembly comprising plunger means has coupling means for engaging the cartridge assembly, and said plunger means is adapted to engage the stopper of the cartridge when the dosing assembly is coupled to the cartridge.

The above-described medication delivery device has fewer parts that the prior art devices because at least one coupling means is moulded unitarily with the cartridge. Thereby the costs involved in the production and assembling of the device are reduced, and the device is more economical, which is an important feature for a disposable device.

The medical delivering device may either be manufactured as a disposable device which is sold pre-filled with the insulin or it may appear as a durable medical delivering device so designed that it can receive disposable cartridges with insulin.

In a preferred embodiment the dosing assembly is reusable and the cartridge assembly is disposable, and accordingly, a second aspect of the present invention is a medication delivery device wherein the dosing assembly is releasably coupled to the cartridge assembly.

The medication delivery device is preferably constructed as to secure that the plunger means abuts on the stopper during use of the device, such as attaching and releasing the needle assembly. It is understood that the plunger means must disengage the stopper when the cartridge assembly is deliberately released from a reusable dosing assembly because the medication in the cartridge has been exhausted and the cartridge assembly is to be discarded. In this situation the plunger means is to be retracted to the dosing assembly before assembling the device with a new cartridge assembly.

Securing the abutment of the plunger means on the stopper during use of the medication delivery device, in particular when the needle assembly is coupled to and/or decoupled from the cartridge assembly, may be carried out by a variety of means. In a preferred embodiment the abutment is secured by preventing the cartridge assembly from being inadvertently released from the dosing assembly.

In particular, when the cartridge assembly is released from the dosing assembly through a movement including an axial movement, such as through a threaded coupling, it is preferred that the means for releasably coupling the needle assembly and the cartridge assembly together are such that the coupling and/or decoupling of the needle assembly cannot cause an axial movement of the cartridge assembly with respect to the dosing assembly. Thus, in that respect examples of the preferred couplings between the needle assembly and the cartridge assembly include releasable snap locks. Another preferred embodiment includes a safety on the coupling between the dosing assembly and the cartridge assembly, such as hinge on the coupling or a threaded coupling releasable only after exerting an axial pressure on the coupling.

A second aspect of the present invention is a cartridge assembly for use in a medication delivery device, said cartridge assembly having one end sealed with a pierceable sealing, said end of the cartridge assembly comprising coupling means for engaging a needle assembly, and another end comprising coupling means for engaging the dosing assembly, said cartridge assembly further comprising a cartridge wherein at least one of the coupling means of said cartridge assembly is unitarily moulded with the cartridge, said cartridge further comprising a stopper.

The cartridge assembly may further comprise a cartridge housing for protecting the cartridge in use. Furthermore, when the cartridge is moulded unitarily with one coupling means the cartridge housing may comprise the other coupling means. Accordingly, in one embodiment of the invention the housing of the cartridge assembly comprises coupling means for coupling the cartridge assembly to the dosing assembly, preferably the coupling means is moulded unitarily with the housing. The cartridge is arranged within the cartridge housing. The cartridge housing may be non-releasably attached to the cartridge, once the cartridge is arranged in the housing, whereby the housing is disposed with the cartridge. In another embodiment the housing is reusable and the cartridge is arranged releasably in the housing.

In a preferred embodiment all the coupling means of the cartridge assembly are unitarily moulded with the cartridge. Thereby, it is possible to construct the cartridge assembly without the housing providing a cartridge assembly with even fewer parts.

The coupling means of the cartridge assembly may be for any suitable coupling, preferably a releasable coupling. Examples of the coupling are snap locks, such as snap locks with guidewire and sideways snap locks, snap locks released through threads, bajonet locks, luer locks, hinged locks, threaded locks and any suitable combinations thereof.

The coupling means unitarily moulded with the cartridge are preferably external coupling means, such as an external threaded coupling.

The cartridge may be moulded from any material suitable for medical containers. The cartridge is preferably moulded from a plastic material, e.g. by injection moulding. A suitable choice of material allows the cartridge to be at least partly transpar-

ent, whereby the user can see whether liquid is left in the cartridge. In a preferred embodiment the cartridge is totally transparent giving the user a greater possibility of inspecting the content of the cartridge.

By using a plastic material as compared to the usual glass material a great advantage is achieved in the production lines. Normally a significant quantity of the produced glass cartridges will be spoiled in the lines due to breakage, however the loss is greatly reduced by the use of plastic cartridges. Furthermore, the risk of small loose glass particles in the cartridges have been eliminated.

The cartridge may be of any suitable form, such as a cylinder. The cylinder may be constructed with various combinations of circular or non-circular inner and outer cross-section. In another embodiment the cartridge may be box-shaped having essentially rectangular or triangular cross-section.

The stopper is in sliding fluid tight engagement in the cartridge. The stopper is preferably made of plastic and/or rubber material.

The flexibility of the cartridge wall is not critical, however if the cartridge is too flexible the function of the stopper may be impaired. Mostly, the cartridge is made of a material only slightly flexible to non-flexible.

In order to enforce and strengthen the cartridge wall the cartridge may be integrally moulded with reinforcements. Thereby, the necessity of a protective housing may be obviated. Furthermore, a scale may be integrally moulded with the cartridge wall providing the user with a measure for the medication used and left.

In a most preferred embodiment the cartridge assembly is comprised only of a cartridge being sealed in one end with a sealing, being unitarily moulded with all couplings means and comprising a stopper.

In a cylindrical cartridge the two couplings of the cartridge assembly are generally opposing each other. However, the coupling for engaging with the dosing assembly being separate from coupling for engaging the needle assembly may be arranged in any angle with respect to the latter coupling.

Another aspect of the present invention is a cartridge being at least partly filled with liquid medication, such as insulin.

Drawings

Fig. 1 is an exploded perspective view of the medication delivery device.

Fig. 2 is a cross-sectional view showing part of the medication delivery device, 2a immediately after assembling before the first injection, and 2b after some time of use.

Fig. 3 is a cross-sectional view showing the cartridge before assembling of the medication delivery device.

Detailed description of the invention

A medication delivery device in accordance with the present invention is identified generally by the numeral 20 in Fig. 1 and 2. Medication delivery device 20 includes a dosing assembly 6, and cartridge assembly 1, a needle assembly 16 and a cap 14.

The dosing assembly 6 is illustrated in Fig. 1 and 2. It is understood, however, that the dosing assembly 6 according to the invention may be any suitable dosing unit including plunger means, and accordingly, that variations from the depicted embodiment may be provided, and are considered to be within the scope of this invention. In the depicted embodiment the dosing assembly 6 includes a cylindrical housing surrounding the plunger means 17 of the dosing unit and having opposed proximal and distal ends.

In one aspect of the invention the plunger means comprises a rod element 7 which is adapted to engage the stopper 4 of the cartridge assembly 1. The rod element 7 advances axially into the cartridge 5 during injections. The dosing assembly may have any suitable driving means for advancing the rod element 7.

The dosing unit 6 preferably also comprises scale means 10 indicating the dosing quantity selected by activating the dose setting means 9 for defining specified selected doses of medication to be delivered. The selected dose may be delivered by actuating the actuator button 18. The actuator button is part of the driving means of the dosing assembly exerting its force on the rod element 7.

The dosing assembly further comprises coupling means 8 adapted for engagement with the cartridge assembly. The coupling means 8 may be internal or external couplings. In a preferred embodiment the coupling 8 is an internal coupling.

The cartridge assembly 1 is illustrated in Fig. 1 and 2, and in greater detail in Fig. 3. In Fig. 1 cartridge assembly 1 includes a moulded cartridge 5 extending from proximal end 21 to distal end 22.

At the distal end 22 of the cartridge assembly 1 is provided coupling means 2 for releasably mounting a needle assembly 11. At the proximal end 21 of the cartridge assembly 1 is provided coupling means 3 for mounting a dosing assembly 6. The coupling means are as described above.

Cartridge 5 also comprises a stopper 4 in sliding fluid tight engagement within said cartridge 5. The stopper 4 is adapted to receive the plunger means, such as a rod element 7 of the dosing assembly 6. The rod element 7 is adapted to exert an axial movement of the stopper 4 towards the sealed end 22 of the cartridge 5.

The cartridge assembly 1 may further comprise a housing for protecting some or all of the cartridge 5. When the cartridge assembly 1 includes a housing, one of the couplings 2, 3 of the cartridge may be moulded unitarily with the housing.

Instead of the protective housing the cartridge 5 may have integrally moulded reinforcements of the cartridge wall.

The depicted cartridge 5 is cylindrical having couplings 2, 3 at opposed ends. However, the cartridge may obtain any suitable form and the cross-section may be circular or non-circular, such as substantially triangular or oval.

The device according to the invention may include a protective cap 14 that is removably mounted over the cartridge assembly 1 and/or the needle 11 and which is removed before injection of the medication in the cartridge 5. The cap further ensures that the content of the cartridge is protected against sunlight.

Referring to Fig. 3 the coupling means of the cartridge are shown in greater detail. The coupling means 3 is an external thread, whereas the coupling means 2 is a recess for a snap lock of the needle assembly. Both coupling means are moulded unitarily with the cartridge.

The various parts of the medication delivery device are advantageously made of plastics, e.g. by injection moulding.

The medication delivery device 20 may further comprise any appropriate needle assembly 11, such as a double ended needle 13 having opposed proximal and distal points and a lumen extending axially therebetween.

A mounting hub 12 is engaged on the needle 13 and is removably connected to the coupling means 2 at the needle end of the cartridge assembly. The relative location of the mounting hub 12 ensures that the proximal point of the needle 13 will pierce the sealing when the mounting hub 12 is engaged with the coupling means 2 on the cartridge assembly 1.

The needle assembly 11 may further comprise a removable shield or cap 15 for protecting against accidental needle sticks.

The device according to the invention is suitable for delivering pre-set dosages of insulin, it is however understood that the device is suitable for the injection of pre-set dosages of other liquids.

In use the user will set the dose by means of the dose setting means 9. Before activating the actuator button 18 the cap 14 must be removed from the cartridge assembly 1 whereby the device 20 is prepared for an injection. The injection is effected by activating the actuator button 18, which again will effect the stopper 4 to be moved towards the sealed end 22 of the cartridge 5, thereby delivering the desi-

red pre-set dosage. A subsequent dosage of medication will be set in exactly the same manner as described above. However, for such a subsequent dosage, the rod element 7 and the stopper 4 will be in a partly advanced position as starting point. Dose setting and injections can be carried out until all of the medication has been used.

Claims:

1. A medication delivery device comprising a cartridge assembly, a dosing assembly and optionally a needle assembly,

said cartridge assembly having one end sealed with a pierceable sealing, said end of the cartridge assembly comprising coupling means for engaging a needle assembly, and another end comprising coupling means for engaging the dosing assembly, said cartridge assembly further comprising a cartridge wherein at least one of the coupling means of said cartridge assembly is unitarily moulded with the cartridge, the cartridge further comprising a stopper adapted to receive plunger means, and

said dosing assembly comprising plunger means having coupling means for engaging the cartridge, and said plunger means is adapted to engage the stopper of the cartridge when the dosing assembly is coupled to the cartridge.

2. A medication delivery device according to claim 1, wherein all the coupling means of the cartridge assembly are unitarily moulded with the cartridge.

3. A medication delivery device according to claim 1 or 2, wherein at least one coupling means of the cartridge is an external coupling.

4. A medication delivery device according to any of the preceding claims, wherein at least one coupling means of the cartridge is a threaded coupling.

5. A medication delivery device according to any of the preceding claims, wherein the cartridge is moulded of a plastic material.

6. A medication delivery device according to any of the preceding claims, wherein the cartridge is at least partly transparent.

7. A medication delivery device according to any of the preceding claims, wherein reinforcements of the cartridge wall are integrally moulded with the cartridge.

8. A medication delivery device according to any of the preceding claims, wherein the cartridge further comprises a cartridge housing.

9. A medication delivery device according to any of the preceding claims, wherein the cartridge further comprise a scale.

10. A medication delivery device according to any of the preceding claims, wherein the cross-section of the cartridge is non-circular.

11. A medication delivery device according to any of the preceding claims, wherein the coupling means of the cartridge are opposed each other.

12. A cartridge assembly for use in a medication delivery device, said cartridge assembly having one end sealed with a pierceable sealing, said end of the cartridge assembly comprising coupling means for engaging a needle assembly, and another end comprising coupling means for engaging the dosing assembly, said cartridge assembly further comprising a cartridge wherein at least one of the coupling means of said cartridge assembly is unitarily moulded with the cartridge, said cartridge further comprising a stopper.

13. A cartridge assembly according to claim 12, wherein all the coupling means of the cartridge are unitarily moulded with the cartridge.

14. A cartridge assembly according to claim 12 or 13, wherein at least one coupling means of the cartridge is an external coupling.

15. A cartridge assembly according to any of the claims 12-14, wherein at least one coupling means of the cartridge is a threaded coupling.

16. A cartridge assembly according to any of the claims 12-15, wherein the cartridge is moulded of a plastic material.

17. A cartridge assembly according to any of the preceding 12-16, wherein the cartridge is at least partly transparent.

18. A cartridge assembly according to any of the claims 12-17, wherein reinforcements of the cartridge wall are integrally moulded with the cartridge.

19. A cartridge assembly according to any of the claims 12-18, wherein the cartridge further comprises a cartridge housing.

20. A cartridge assembly according to any of the claims 12-19, wherein the cartridge further comprise a scale.

21. A cartridge assembly according to any of the claims 12-20, wherein the cross-section of the cartridge is non-circular.

22. A cartridge assembly according to any of the claims 12-21, wherein the coupling means of the cartridge are opposed each other.

23. A cartridge assembly according to any of the claims 12-22, which is filled with medicine.

Attorney Docket No.: 5637.003-US PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

FILING UNDER 37 C.F.R. §1.53(c)

Assistant Commissioner for Patents
Washington, DC 20231

Express Mail Label No. TB265589918US
Date of Deposit September 1, 1998

Sir:

This is a request for filing a **Provisional** application under 37 C.F.R. §1.53(c), of the inventors:

Thomas **BUCH-RASMUSSEN**, a citizen of Denmark residing at Dalvej 28, DK-2820 Gentofte, Denmark;

Benny **MUNK**, a citizen of Denmark, residing at Baeverskov Alle 52, DK-2720 Vanlose, Denmark;

Jens Ulrik **POULSEN**, a citizen of Denmark, residing at Virumgade 54 C, DK-2830 Virum, Denmark;

Henrik **LJUNGREEN**, a citizen of Denmark, residing at Jonstrupvej 244 A, DK-2750 Ballerup, Denmark;

Peter Moller **JENSEN**, a citizen of Denmark, residing at Svenstrupvej 6, DK-2970 Horsholm, Denmark; and

Jens Moller **JENSEN**, a citizen of Denmark, residing at Nyhavn 37, DK-1051 Kobenhavn K, Denmark.

for application entitled: **"MEDICAL DEVICE"**.

The provisional application contains:

12 pages of specification

2 sheets of drawings

Address all future communications to Steve T. Zelson, Esq., Novo Nordisk of North America, Inc., 405 Lexington Avenue, Suite 6400, New York, NY 10174-6401.

Please charge the required fee, estimated to be $150, to Novo Nordisk of North America, Inc., Deposit Account No. 14-1447. A duplicate of this sheet is enclosed.

Respectfully submitted,

Date: September 1, 1998

Carol E. Rozek

Carol E. Rozek, Reg. No. 36,993
Novo Nordisk of North America, Inc.
405 Lexington Avenue, Suite 6400
New York, NY 10174-6401
(212) 867-0123

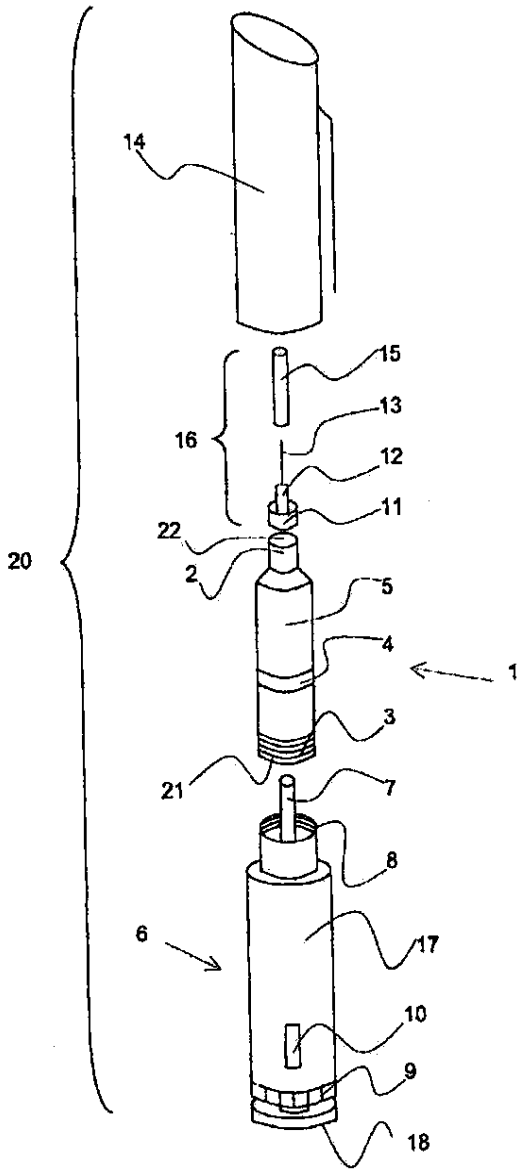

Fig. 1

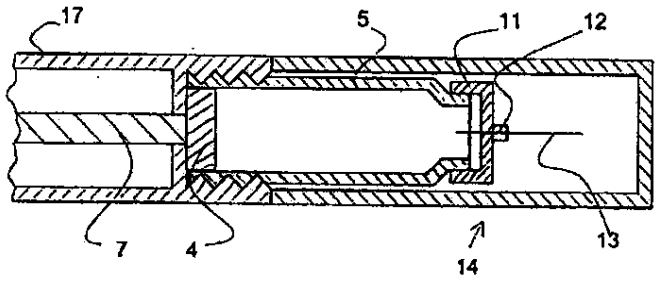

Fig. 2 a

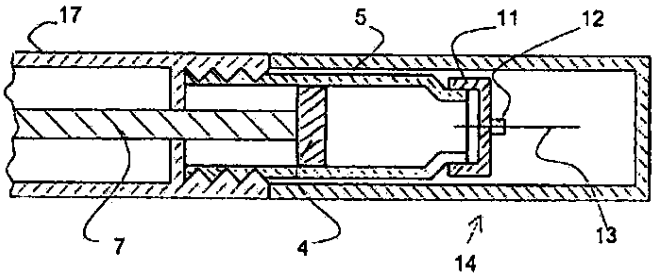

Fig. 2 b

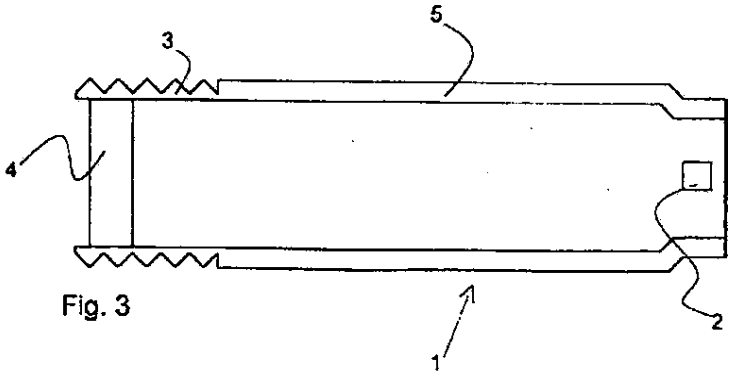

Fig. 3

SERIAL NUMBER	FILING DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
60/098,702 PROVISIONAL	09/01/98		0000	5637.003-US

APPLICANT

THOMAS BUCH-RASMUSSEN, GENTOFTE, DENMARK; KUNK BENNY, VANLOSE, DENMARK; HENRIK LJUNGREEN, BALLERUP, DENMARK; PETER M. JENSEN, HORSHOLM, DENMARK; JENS M. JENSEN, KOBENHAVN K, DENMARK.

CONTINUING DOMESTIC DATA********
VERIFIED

371 (NAT'L STAGE) DATA********
VERIFIED

FOREIGN APPLICATIONS********
VERIFIED

IF REQUIRED, FOREIGN FILING LICENSE GRANTED 07/26/99

Foreign Priority claimed 35 USC 119 (a-d) conditions met / Verified and Acknowledged	STATE OR COUNTRY	SHEETS DRAWING	TOTAL CLAIMS	INDEPENDENT CLAIMS
☐yes ☐no ☐yes ☐no ☐Met after Allowance EXAMINER'S INITIALS _____	DKX	2		

ADDRESS

NOVO NORDISK OF NORTH AMERICA INC
405 LEXINGTON AVENUE STE 6400
NEW YORK NY 10017

TITLE

MEDICAL DEVICE

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Attorney Docket No.: 5637.003-US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

EXPRESS MAIL CERTIFICATE

Assistant Commissioner for Patents
Washington, DC 20231

Re: U.S. Provisional Application for
"Medical Device"
Applicants: Buch-Rasmussen et al.

Sir:

Express Mail Label No. TB265589918US

Date of Deposit September 1, 1998

I hereby certify that the following attached paper(s) or fee

1. Filing Under 37 C.F.R. §1.53(c) (in duplicate)
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are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" under 37 C.F.R. 1.10 on the date indicated above and is addressed to the Commissioner of Patents and Trademarks, Washington, DC 20231.

Miriam Kelly
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Miriam Kelly
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Mailing Address:

Novo Nordisk of North America, Inc.
405 Lexington Avenue, Suite 6400
New York, NY 10017
(212) 867-0123

Receipt

Attorney Docket No.: 5637.003-US PATENT #2

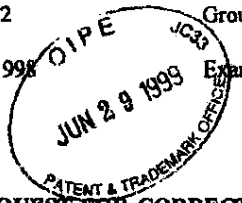
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Buch-Rasmussen et al.

Serial No.: 60/098,702 Group Art Unit: to be assigned

Filed: September 1, 1998 Examiner: to be assigned

For: Medical Device



REQUEST FOR CORRECTED FILING RECEIPT

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

Applicant filed the above-captioned application on September 1, 1998.

The filing receipt received by Applicant incorrectly indicated that the filing date is **09/10/98**. A copy of the filing receipt is attached to this request.

Applicant therefore requests the issuance of a corrected filing receipt with revised filing date to **09/01/98**.

Applicant submits that the error was the fault of the USPTO. Therefore, a fee for this service is not required.

Respectfully submitted,

Date: June 25, 1999

Carol E. Rozek, Reg. No. 36,993
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New York, NY 10174-6401
(212) 867-0123

Attorney Docket No.: 5637.003-US PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Buch-Rasmussen et al.

Serial No.: 60/098,702 Group Art Unit: to be assigned

Filed: September 1, 1998 Examiner: to be assigned

For: Medical Device

CERTIFICATE OF MAILING UNDER 37 CFR 1.8(a)

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

I hereby certify that the attached correspondence comprising:

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Miriam Kelly
(name of person mailing paper)

Miriam Kelly
(signature of person mailing paper)

TO-103P
(rev. 8-96)

PROVISIONAL APPLICATION
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APPLICATION NUMBER	FILING DATE	FIL FEE REC'D	ATTO...Y DOCKET NO.	DRWGS
60/098,792	09/10/98	$150.00	5637.003-US	2

NOVO NORDISK OF NORTH AMERICA INC
405 LEXINGTON AVENUE STE 6400
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OIPE JC33 JUN 29 1999 PATENT & TRADEMARK OFFICE

Receipt is acknowledged of this Provisional Application. This Provisional Application will not be examined for patentability. Be sure to provide the PROVISIONAL APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please write to the Provisional Application Division within 10 days of receipt. Please provide a copy of the Provisional Application Filing Receipt with the changes noted thereon. This Provisional Application will automatically be abandoned twelve (12) months after its filing date and will not be subject to revival to restore it to pending status beyond a date which is after twelve (12) months from its filing date.

Applicant(s) THOMAS BUCH-RASMUSSEN, GENTOFTE, DENMARK; MUNK BENNY, VANLOSE, DENMARK; HENRIK LJUNGREEN, BALLERUP, DENMARK; PETER M. JENSEN, HORSHOLM, DENMARK; JENS M. JENSEN, KOBENHAVN K, DENMARK.

TITLE
MEDICAL DEVICE

9/1/98

(see reverse)

PTO/SB/68 (06-03)
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REQUEST FOR ACCESS TO AN ABANDONED APPLICATION UNDER 37 CFR 1.14

Bring completed form to:
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Telephone: (703) 308-2733

In re Application of

Application Number	Filed
60-098702	9-1-98

Paper No. #3

I hereby request access under 37 CFR 1.14(a)(1)(iv) to the application file record of the above-identified ABANDONED application, which is identified in, or to which a benefit is claimed, in the following document (as shown in the attachment):

United States Patent Application Publication No. _____, page, _____ line _____,

United States Patent Number 6562011, column _____, line, _____ or

WIPO Pub. No._____, page _____, line _____.

Related Information about Access to Pending Applications (37 CFR 1.14):
Direct access to pending applications is not available to the public (see 37 CFR 1.14(c) if applicant) but copies may be available and may be purchased from the Office of Public Records upon payment of the appropriate fee (37 CFR 1.19(b)), as follows:

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Darlene Jones
Signature

7/18/06
Date

Darlene Jones
Typed or printed name

Registration Number, if applicable

713 448 0330
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This collection of information is required by 37 CFR 1.14. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. BRING TO: File Information Unit, Crystal Plaza Three, Room 1D01, 2021 South Clark Place, Arlington, VA.

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#3

US006562011B1

(12) **United States Patent**
Buch-Rasmussen et al.

(10) **Patent No.: US 6,562,011 B1**
(45) **Date of Patent: May 13, 2003**

(54) **MEDICATION DELIVERY DEVICE**

(75) Inventors: Thomas Buch-Rasmussen, Gentofte (DK); Benny Munk, Hvidovre (DK); Jens Ulrik Poulsen, Virum (DK); Henrik Ljungreen, Ballerup (DK); Peter Møller Jensen, Hjørholm (DK); Jens Møller Jensen, Copenhagen (DK)

(73) Assignee: Novo Nordisk A/S, Bagsværd (DK)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: 09/348,536

(22) Filed: Jul. 7, 1999

Related U.S. Application Data

(60) Provisional application No. 60/092,703, filed on Sep. 4, 1998.

(30) **Foreign Application Priority Data**

Jul. 8, 1998 (DK) 1998 00909
Nov. 17, 1998 (DK) 1998 01500

(51) Int. Cl.[7] A61M 5/00
(52) U.S. Cl. 604/232
(58) Field of Search 604/200-201, 604/228, 232-234

(56) **References Cited**

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WO	WO 97/40820	12/1997

* cited by examiner

Primary Examiner—Brian L. Casler
Assistant Examiner—Kevin C. Sirmons
(74) *Attorney, Agent, or Firm*—Marc A. Began, Esq.; Richard W. Bork, Esq.; Reza Green, Esq.

(57) **ABSTRACT**

The present invention relates to a medication delivery device comprising a cartridge assembly, a dosing assembly and optionally a needle assembly. The cartridge assembly comprises a cartridge having a stopper adapted to receive a plunger means. Furthermore, the cartridge assembly has one end sealed with a pierceable sealing, said end comprising coupling means for engaging a needle assembly, and another end comprising coupling means for engaging the dosing assembly. At least one of the coupling means of the cartridge assembly is unitarily moulded with the cartridge. The dosing assembly comprises a plunger means and has coupling means for engaging the cartridge assembly. The cartridge assembly and the dosing assembly are coupled together for delivering selected doses of medication. The cartridge is preferably moulded from a plastic material, such as a transparent material, and may be housed in a cartridge housing for protection of the cartridge. The coupling means may be selected from threaded locks, snap locks, hinged locks, or bajonet locks. The medication delivery device is especially suitable for delivering insulin, growth hormone or other medicines.

7 Claims, 2 Drawing Sheets

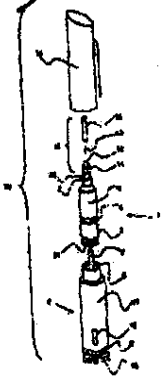

EXHIBIT 9

Kongeriget Danmark

Patent application No.: PA 1998 01500

Date of filing: 17 November 1998

Applicant: Novo Nordisk A/S
Novo Allé
DK-2880 Bagsværd

This is to certify the correctness of the following information:

The attached photocopy is a true copy of the following information:

- The specification, claims and figures as filed with the application on the filing date indicated above.

Patent- og Varemærkestyrelsen
Økonomi- og Erhvervsministeriet

TAASTRUP 03 December 2002

Karin Schlichting
Head Clerk
PATENT- OG VAREMÆRKESTYRELSEN

The present invention relates to a medication delivery device having a cartridge and a dosing assembly coupled together for delivering selected doses of medication, wherein at least one of the coupling means of the cartridge is unitarily moulded with the cartridge.

Background

Some medication, such as insulin is self-administered. The typical diabetes patient will require injections of insulin several times during the day. The required insulin dose will vary from patient to patient, and will for each patient often also vary during the day. Each patient will often establish a regimen for the insulin administration adjusted to his or her insulin need as well as lifestyle. Medication delivery pens have been developed to facilitate the self-administration of medication, such as insulin.

One prior art medication delivery pen includes a pen body assembly comprising a medication cartridge and a plunger device. A needle assembly may be connected to the pen body assembly. The medication is delivered by moving or pressing a plunger in the direction of the needle assembly thereby delivering the medication. When the medication in the cartridge is exhausted the pen body assembly is discarded. Depending on the medication needs for each individual the medication in the cartridge will last for several days. During this period the needle assembly will often have to be displaced by a new assembly or new needle due to increasing bluntness of the needle making injections painful for the patient.

More recent developments have revealed medication delivery pens, wherein the cartridge holder assembly can be disassembled from the pen body assembly after the medication therein has been exhausted, discarded and replaced by a new medicine-containing cartridge assembly.

An example of this is shown in EP 0 688 571 disclosing a medication delivery pen having a reusable pen body assembly and a disposable cartridge assembly that are threadedly engageable with one another. The cartridge assembly comprises a cartridge, a cartridge housing, a cap between the distal end of the cartridge and the housing, securing the cartridge in the housing and being adapted for engagement

with a needle assembly. Furthermore, the cartridge comprises a plunger within the cartridge. The reusable pen body assembly is coupled through a threaded coupling to the cartridge housing. Thus, the total number of parts comprising the prior art cartridge assembly is high.

It is an object of the present invention to provide a medicaiton delivery device wherein the amount of parts of the cartridge is minimised.

Summary of the Invention

Accordingly, the present invention relates to a medication delivery device comprising a cartridge assembly, a dosing assembly and optionally a needle assembly,

said cartridge assembly having one end sealed with a piercable sealing, said end of the cartridge assembly comprising coupling means for engaging a needle assembly, and another end comprising coupling means for engaging the dosing assembly, said cartridge assembly further comprising a cartridge wherein at least one of the coupling means of said cartridge assembly is unitarily moulded with the cartridge, the cartridge further comprising a stopper adapted to receive plunger means, and

said dosing assembly comprising plunger means has coupling means for engaging the cartridge assembly, and said plunger means is adapted to engage the stopper of the cartridge when the dosing assembly is coupled to the cartridge.

The above-described medication delivery device has fewer parts that the prior art devices because at least one coupling means is moulded unitarily with the cartridge. Thereby the costs involved in the production and assembling of the device are reduced, and the device is more economical, which is an important feature for a disposable device.

The medical delivering device may either be manufactured as a disposable device which is sold pre-filled with the insulin or it may appear as a durable medical delivering device so designed that it can receive disposable cartridges with insulin.

In a preferred embodiment the dosing assembly is reusable and the cartridge assembly is disposable, and accordingly, a second aspect of the present invention is a medication delivery device wherein the dosing assembly is releasably coupled to the cartridge assembly.

The medication delivery device is preferably constructed as to secure that the plunger means abuts on the stopper during use of the device, such as attaching and releasing the needle assembly. It is understood that the plunger means must disengage the stopper when the cartridge assembly is deliberately released from a reusable dosing assembly because the medication in the cartridge has been exhausted and the cartridge assembly is to be discarded. In this situation the plunger means is to be retracted to the dosing assembly before assembling the device with a new cartridge assembly.

Securing the abutment of the plunger means on the stopper during use of the medication delivery device, in particular when the needle assembly is coupled to and/or decoupled from the cartridge assembly, may be carried out by a variety of means. In a preferred embodiment the abutment is secured by preventing the cartridge assembly from being inadvertently released from the dosing assembly.

In particular, when the cartridge assembly is released from the dosing assembly through a movement including an axial movement, such as through a threaded coupling, it is preferred that the means for releasably coupling the needle assembly and the cartridge assembly together are such that the coupling and/or decoupling of the needle assembly cannot cause an axial movement of the cartridge assembly with respect to the dosing assembly. Thus, in that respect examples of the preferred couplings between the needle assembly and the cartridge assembly include releasable snap locks. Another preferred embodiment includes a safety on the coupling between the dosing assembly and the cartridge assembly, such as hinge on the coupling or a threaded coupling releasable only after exerting an axial pressure on the coupling.

A second aspect of the present invention is a cartridge assembly for use in a medication delivery device, said cartridge assembly having one end sealed with a pierceable sealing, said end of the cartridge assembly comprising coupling means for engaging a needle assembly, and another end comprising coupling means for engaging the dosing assembly, said cartridge assembly further comprising a cartridge wherein at least one of the coupling means of said cartridge assembly is unitarily moulded with the cartridge, said cartridge further comprising a stopper.

The cartridge assembly may further comprise a cartridge housing for protecting the cartridge in use. Furthermore, when the cartridge is moulded unitarily with one coupling means the cartridge housing may comprise the other coupling means. Accordingly, in one embodiment of the invention the housing of the cartridge assembly comprises coupling means for coupling the cartridge assembly to the dosing assembly, preferably the coupling means is moulded unitarily with the housing. The cartridge is arranged within the cartridge housing. The cartridge housing may be non-releasably attached to the cartridge, once the cartridge is arranged in the housing, whereby the housing is disposed with the cartridge. In another embodiment the housing is reusable and the cartridge is arranged releasably in the housing.

In a preferred embodiment all the coupling means of the cartridge assembly are unitarily moulded with the cartridge. Thereby, it is possible to construct the cartridge assembly without the housing providing a cartridge assembly with even fewer parts.

The coupling means of the cartridge assembly may be for any suitable coupling, preferably a releasable coupling. Examples of the coupling are snap locks, such as snap locks with guidewire and sideways snap locks, snap locks released through threads, bajonet locks, luer locks, hinged locks, threaded locks and any suitable combinations thereof.

The coupling means unitarily moulded with the cartridge are preferably external coupling means, such as an external threaded coupling.

The cartridge may be moulded from any material suitable for medical containers. The cartridge is preferably moulded from a plastic material, e.g. by injection moulding. A suitable choice of material allows the cartridge to be at least partly transpar-

ent, whereby the user can see whether liquid is left in the cartridge. In a preferred embodiment the cartridge is totally transparent giving the user a greater possibility of inspecting the content of the cartridge.

By using a plastic material as compared to the usual glass material a great advantage is achieved in the production lines. Normally a significant quantity of the produced glass cartridges will be spoiled in the lines due to breakage, however the loss is greatly reduced by the use of plastic cartridges. Furthermore, the risk of small loose glass particles in the cartridges have been eliminated.

The cartridge may be of any suitable form, such as a cylinder. The cylinder may be constructed with various combinations of circular or non-circular inner and outer cross-section. In another embodiment the cartridge may be box-shaped having essentially rectangular or triangular cross-section.

The stopper is in sliding fluid tight engagement in the cartridge. The stopper is preferably made of plastic and/or rubber material.

The flexibility of the cartridge wall is not critical, however if the cartridge is too flexible the function of the stopper may be impaired. Mostly, the cartridge is made of a material only slightly flexible to non-flexible.

In order to enforce and strengthen the cartridge wall the cartridge may be integrally moulded with reinforcements. Thereby, the necessity of a protective housing may be obviated. Furthermore, a scale may be integrally moulded with the cartridge wall providing the user with a measure for the medication used and left.

In a most preferred embodiment the cartridge assembly is comprised only of a cartridge being sealed in one end with a sealing, being unitarily moulded with all couplings means and comprising a stopper.

In a cylindrical cartridge the two couplings of the cartridge assembly are generally opposing each other. However, the coupling for engaging with the dosing assembly being separate from coupling for engaging the needle assembly may be arranged in any angle with respect to the latter coupling.

Another aspect of the present invention is a cartridge being at least partly filled with liquid medication, such as insulin.

In another embodiment the invention relates to a medication delivery device for transferring medication from the cartridge into a syringe with a needle. In this embodiment the coupling means for engaging the needle assembly may be replaced by coupling means for engaging the syringe, or coupling means for both may be provided. The coupling means may be a syringe holder, for example a cylinder coupled to the cartridge comprising a central bore for receiving the syringe. The syringe is coupled to the cartridge having the needle piercing the sealing. By activation of the dosing means the metered amount of medication is driven into the syringe. The syringe is then ready for injection after being removed from the cartridge.

Drawings

Fig. 1 is an exploded perspective view of the medication delivery device.

Fig. 2 is a cross-sectional view showing part of the medication delivery device, 2a immediately after assembling before the first injection, and 2b after some time of use.

Fig. 3 is a cross-sectional view showing the cartridge before assembling of the medication delivery device.

Detailed description of the invention

A medication delivery device in accordance with the present invention is identified generally by the numeral 20 in Fig. 1 and 2. Medication delivery device 20 includes a dosing assembly 6, and cartridge assembly 1, a needle assembly 18 and a cap 14.

The dosing assembly 6 is illustrated in Fig. 1 and 2. It is understood, however, that the dosing assembly 6 according to the invention may be any suitable dosing unit including plunger means, and accordingly, that variations from the depicted embodiment may be provided, and are considered to be within the scope of this inven-

tion. In the depicted embodiment the dosing assembly 6 includes a cylindrical housing surrounding the plunger means 17 of the dosing unit and having opposed proximal and distal ends.

In one aspect of the invention the plunger means comprises a rod element 7 which is adapted to engage the stopper 4 of the cartridge assembly 1. The rod element 7 advances axially into the cartridge 5 during injections. The dosing assembly may have any suitable driving means for advancing the rod element 7.

The dosing unit 6 preferably also comprises scale means 10 indicating the dosing quantity selected by activating the dose setting means 9 for defining specified selected doses of medication to be delivered. The selected dose may be delivered by actuating the actuator button 18. The actuator button is part of the driving means of the dosing assembly exerting its force on the rod element 7.

The dosing assembly further comprises coupling means 8 adapted for engagement with the cartridge assembly. The coupling means 8 may be internal or external couplings. In a preferred embodiment the coupling 8 is an internal coupling.

The cartridge assembly 1 is illustrated in Fig. 1 and 2, and in greater detail in Fig. 3. In Fig. 1 cartridge assembly 1 includes a moulded cartridge 5 extending from proximal end 21 to distal end 22.

At the distal end 22 of the cartridge assembly 1 is provided coupling means 2 for releasably mounting a needle assembly 11. At the proximal end 21 of the cartridge assembly 1 is provided coupling means 3 for mounting a dosing assembly 6. The coupling means are as described above.

Cartridge 5 also comprises a stopper 4 in sliding fluid tight engagement within said cartridge 5. The stopper 4 is adapted to receive the plunger means, such as a rod element 7 of the dosing assembly 6. The rod element 7 is adapted to exert an axial movement of the stopper 4 towards the sealed end 22 of the cartridge 5.

The cartridge assembly 1 may further comprise a housing for protecting some or all of the cartridge 5. When the cartridge assembly 1 includes a housing, one of the couplings 2, 3 of the cartridge may be moulded unitarily with the housing.

Instead of the protective housing the cartridge 5 may have integrally moulded reinforcements of the cartridge wall.

The depicted cartridge 5 is cylindrical having couplings 2, 3 at opposed ends. However, the cartridge may obtain any suitable form and the cross-section may be circular or non-circular, such as substantially triangular or oval.

The device according to the invention may include a protective cap 14 that is removably mounted over the cartridge assembly 1 and/or the needle 11 and which is removed before injection of the medication in the cartridge 5. The cap further ensures that the content of the cartridge is protected against sunlight.

Referring to Fig. 3 the coupling means of the cartridge are shown in greater detail. The coupling means 3 is an external thread, whereas the coupling means 2 is a recess for a snap lock of the needle assembly. Both coupling means are moulded unitarily with the cartridge.

The various parts of the medication delivery device are advantageously made of plastics, e.g. by injection moulding.

The medication delivery device 20 may further comprise any appropriate needle assembly 11, such as a double ended needle 13 having opposed proximal and distal points and a lumen extending axially therebetween.

A mounting hub 12 is engaged on the needle 13 and is removably connected to the coupling means 2 at the needle end of the cartridge assembly. The relative location of the mounting hub 12 ensures that the proximal point of the needle 13 will pierce the sealing when the mounting hub 12 is engaged with the coupling means 2 on the cartridge assembly 1.

The needle assembly 11 may further comprise a removable shield or cap 15 for protecting against accidental needle sticks.

The device according to the invention is suitable for delivering pre-set dosages of insulin, it is however understood that the device is suitable for the injection of pre-set dosages of other liquids.

In use the user will set the dose by means of the dose setting means 9. Before activating the actuator button 18 the cap 14 must be removed from the cartridge assembly 1 whereby the device 20 is prepared for an injection. The injection is effected by activating the actuator button 18, which again will effect the stopper 4 to be moved towards the sealed end 22 of the cartridge 5, thereby delivering the desired pre-set dosage. A subsequent dosage of medication will be set in exactly the same manner as described above. However, for such a subsequent dosage, the rod element 7 and the stopper 4 will be in a partly advanced position as starting point. Dose setting and injections can be carried out until all of the medication has been used.

Claims:

1. A medication delivery device comprising a cartridge assembly, a dosing assembly and optionally a needle assembly,

said cartridge assembly having one end sealed with a pierceable sealing, said end of the cartridge assembly comprising coupling means for engaging a needle assembly, and another end comprising coupling means for engaging the dosing assembly, said cartridge assembly further comprising a cartridge wherein at least one of the coupling means of said cartridge assembly is unitarily moulded with the cartridge, the cartridge further comprising a stopper adapted to receive plunger means, and

said dosing assembly comprising plunger means having coupling means for engaging the cartridge, and said plunger means is adapted to engage the stopper of the cartridge when the dosing assembly is coupled to the cartridge.

2. A medication delivery device according to claim 1, wherein all the coupling means of the cartridge assembly are unitarily moulded with the cartridge.

3. A medication delivery device according to claim 1 or 2, wherein at least one coupling means of the cartridge is an external coupling.

4. A medication delivery device according to any of the preceding claims, wherein at least one coupling means of the cartridge is a threaded coupling.

5. A medication delivery device according to any of the preceding claims, wherein the cartridge is moulded of a plastic material.

6. A medication delivery device according to any of the preceding claims, wherein the cartridge is at least partly transparent.

7. A medication delivery device according to any of the preceding claims, wherein reinforcements of the cartridge wall are integrally moulded with the cartridge.

8. A medication delivery device according to any of the preceding claims, wherein the cartridge further comprises a cartridge housing.

9. A medication delivery device according to any of the preceding claims, wherein the cartridge further comprise a scale.

10. A medication delivery device according to any of the preceding claims, wherein the cross-section of the cartridge is non-circular.

11. A medication delivery device according to any of the preceding claims, wherein the coupling means of the cartridge are opposed each other.

12. A cartridge assembly for use in a medication delivery device, said cartridge assembly having one end sealed with a pierceable sealing, said end of the cartridge assembly comprising coupling means for engaging a needle assembly, and another end comprising coupling means for engaging the dosing assembly, said cartridge assembly further comprising a cartridge wherein at least one of the coupling means of said cartridge assembly is unitarily moulded with the cartridge, said cartridge further comprising a stopper.

13. A cartridge assembly according to claim 12, wherein all the coupling means of the cartridge are unitarily moulded with the cartridge.

14. A cartridge assembly according to claim 12 or 13, wherein at least one coupling means of the cartridge is an external coupling.

15. A cartridge assembly according to any of the claims 12-14, wherein at least one coupling means of the cartridge is a threaded coupling.

16. A cartridge assembly according to any of the claims 12-15, wherein the cartridge is moulded of a plastic material.

17. A cartridge assembly according to any of the preceding 12-16, wherein the cartridge is at least partly transparent.

18. A cartridge assembly according to any of the claims 12-17, wherein reinforcements of the cartridge wall are integrally moulded with the cartridge.

19. A cartridge assembly according to any of the claims 12-18, wherein the cartridge further comprises a cartridge housing.

20. A cartridge assembly according to any of the claims 12-19, wherein the cartridge further comprise a scale.

21. A cartridge assembly according to any of the claims 12-20, wherein the cross-section of the cartridge is non-circular.

22. A cartridge assembly according to any of the claims 12-21, wherein the coupling means of the cartridge are opposed each other.

23. A cartridge assembly according to any of the claims 12-22, which is filled with medicine.

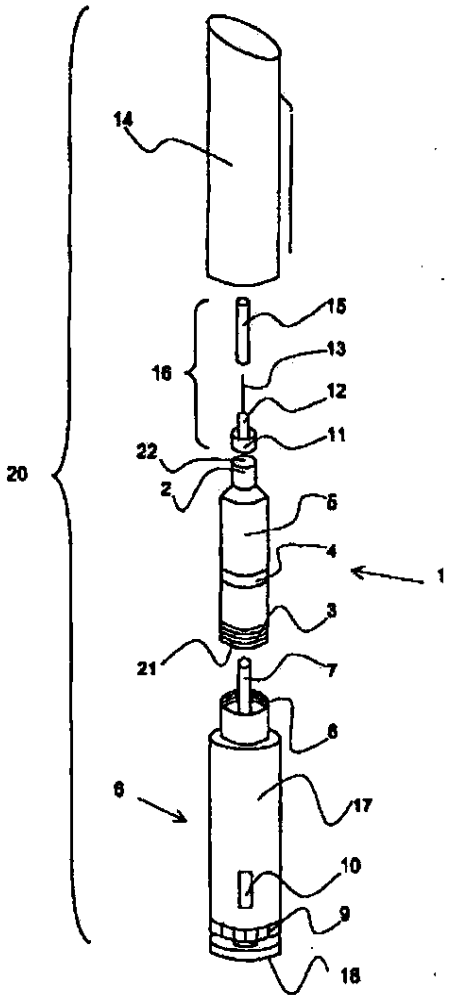

Fig. 1

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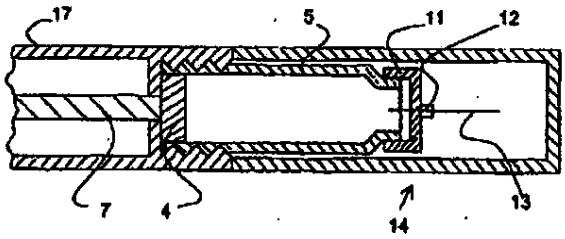

Fig. 2 a

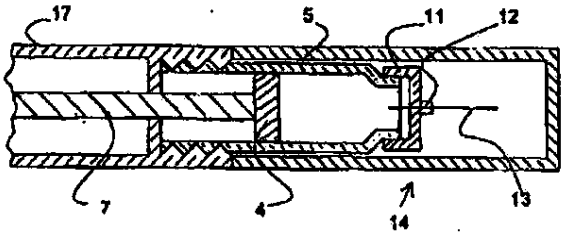

Fig. 2 b

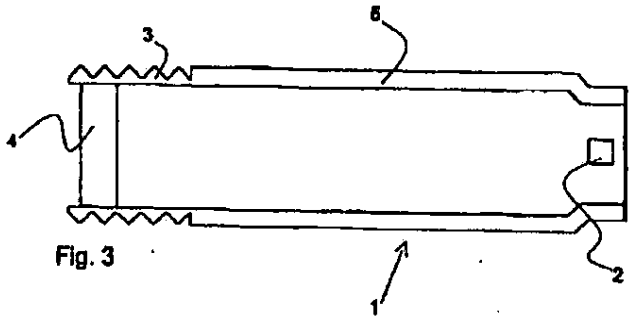

Fig. 3

EXHIBIT 10

ISSUE CLASSIFICATION	
Class	Subclass
604	207

[redacted]

PATENT NUMBER
6004297
6004297

U.S. UTILITY PATENT APPLICATION

O.I.P.E.	PATENT DATE
SCANNED A.G.S. Q.A.	DEC 21 1999

SECTOR	CLASS	SUBCLASS	ART UNIT	EXAMINER
	604	207	3734	YASKO

FILED WITH: ☐ DISK (CRF) ☐ FICHE
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PREPARED AND APPROVED FOR ISSUE

ISSUING CLASSIFICATION

ORIGINAL		CROSS REFERENCE(S)	
CLASS	SUBCLASS	CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)

INTERNATIONAL CLASSIFICATION

☐ Continued on Issue Slip Inside File Jacket

12/8/99 Formal Drawings (5 shts) set 1 12/15/99

☐ TERMINAL DISCLAIMER	DRAWINGS			8-5 CLAIMS ALLOWED	
	Sheets Drwg.	Figs. Drwg.	Print Fig.	Total Claims	Print Claim for O.G.
	5	17	2	8	1

☐ a) The term of this patent subsequent to _____ (date) has been disclaimed.
(Assistant Examiner) (Date)

NOTICE OF ALLOWANCE MAILED
8/5/99

☐ b) The term of this patent shall not extend beyond the expiration date of U.S Patent. No. _____
JOHN D. YASKO 8-5-99
(Primary Examiner) (Date)

ISSUE FEE JH

Amount Due	Date Paid
$1210.—	8-30-99

☐ c) The terminal ____months of this patent have been disclaimed.
(Legal Instruments Examiner) (Date)

ISSUE BATCH NUMBER
W78

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Formal Drawings (____shts) set____

ISSUE FEE IN FILE

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jc551 U.S. PTO
09/238849
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PATENT APPLICATION

09238849

CONTENTS

	Date received (Incl. C. of M.) or Date Mailed		Date received (Incl. C. of M.) or Date Mailed
1. Application _____ papers.		42.	
2. Pre Amdt A	1-29-99	43.	
3. Priority Paper	1-28-99	44.	
4. QUAYLE (2 mos)	6-7-99 5-26	45.	
5. Response w/ Missing Part	6-21-99	46.	
6. Amdt B w/	7-26-99	47.	
7. Notice of Abandonment	8/5/99	48.	
8. IDS	8-12-99	49.	
9. Letter	11-29-99	50.	
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ISSUE SLIP STAPLE AREA (for additional cross references)

POSITION	INITIALS	ID NO.	DATE
FEE DETERMINATION	TD		2/3/99
O.I.P.E. CLASSIFIER	DM	69300	2/8
FORMALITY REVIEW			

INDEX OF CLAIMS

✔ ..... Rejected
= ..... Allowed
— (Through numeral) Canceled
÷ ..... Restricted
N ..... Non-elected
I ..... Interference
A ..... Appeal
O ..... Objected

Claim Final	Claim Original	Date
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STAPLE AREA

U.S. GOVERNMENT PRINTING OFFICE: 1996-440-769

PATENT NUMBER

APPLICATION SERIAL NUMBER
238849

APPLICANT'S NAME (PLEASE PRINT)
JENSEN et al

IF REISSUE, ORIGINAL PATENT NUMBER

INTERNATIONAL CLASSIFICATION
A 61 M 5/00

ORIGINAL CLASSIFICATION

CLASS	SUBCLASS
604	207

CROSS REFERENCE(S)

CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)
604	211

GROUP ART UNIT
3763

ASSISTANT EXAMINER (PLEASE STAMP OR PRINT FULL NAME)

PRIMARY EXAMINER (PLEASE STAMP OR PRINT FULL NAME)
JOHN D. YASKO

PTO 270 (REV. 6-91)

ISSUE CLASSIFICATION SLIP

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

[redacted]

SEARCHED

Class	Sub.	Date	Exmr.
604	207 208 211 218 232	5-25-99	J.Y.

SEARCH NOTES
(INCLUDING SEARCH STRATEGY)

	Date	Exmr.

INTERFERENCE SEARCHED

Class	Sub.	Date	Exmr.
604	same as above	8-5-99	JY

(RIGHT OUTSIDE)

US006004297A

United States Patent [19]

Steenfeldt-Jensen et al.

[11] **Patent Number: 6,004,297**

[45] **Date of Patent: Dec. 21, 1999**

[54] **INJECTION SYRINGE**

[75] Inventors: **Søren Steenfeldt-Jensen**, Hornbæk; **Steffen Hansen**, Hillerød, both of Denmark

[73] Assignee: **Novo Nordisk A/S**, Bagsvaerd, Denmark

[21] Appl. No.: **09/238,849**

[22] Filed: **Jan. 28, 1999**

Related U.S. Application Data

[60] Provisional application No. 60/073,820, Feb. 5, 1998.

[30] **Foreign Application Priority Data**

Jan. 30, 1998 [DK] Denmark 00130/98

[51] **Int. Cl.**[6] **A61M 5/00**

[52] **U.S. Cl.** **604/207**; 604/211

[58] **Field of Search** 604/207, 208, 604/211, 218, 232

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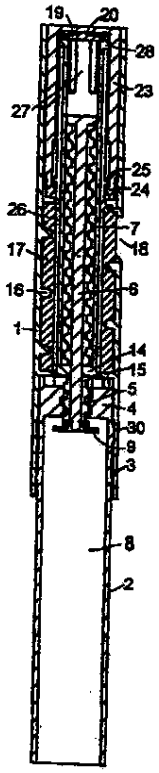
93/07922	4/1993	WIPO .

Primary Examiner—John D. Yasko
Attorney, Agent, or Firm—Steve T. Zelson, Esq.

[57] **ABSTRACT**

An injection syringe comprises a housing (1), a piston rod (6) with a non-circular cross-section and an outer thread (7), a piston rod drive which includes a piston rod guide (85) mating with the cross-section of the piston rod (6), and a nut (4) which is not axially displaceable and which mates with the thread (7) of the piston rod (6) to form a self-locking thread connection. Rotation of a dose setting element (81) causes an injection button to be screwed out to project from the housing (1). When the injection button (88) is pushed axially, such axial movement is transformed, by way of the threaded coupling, into a rotation of one of the piston drive elements (85) relative to the other one (4). A unidirectional coupling between the nut member (4) and the piston rod guide (85) allows rotation in one direction by which the piston rod (6) is transported in a distal direction. The coupling has an initial reluctance to be overcome before rotation takes place, said reluctance being large enough to resist torques exerted during the dose setting.

8 Claims, 5 Drawing Sheets



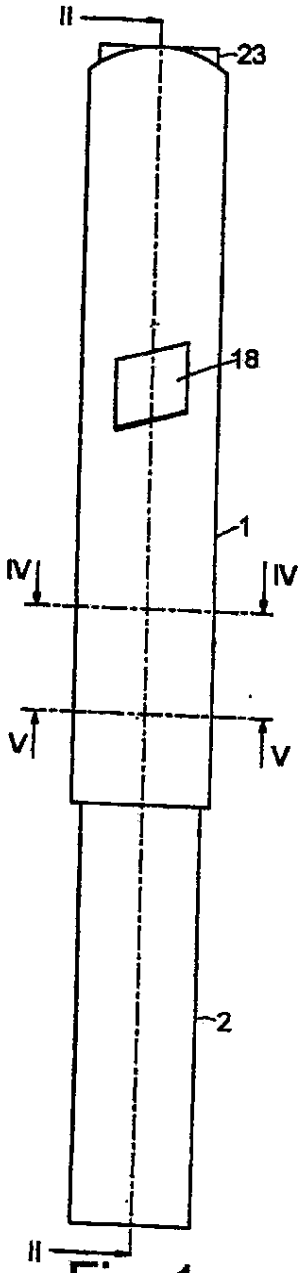


Fig. 1

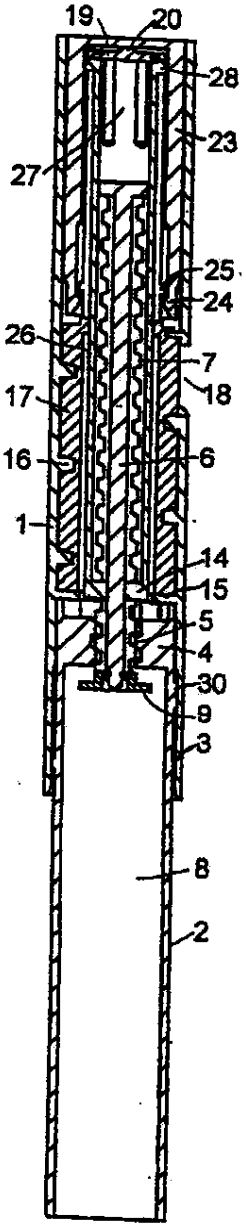


Fig.2

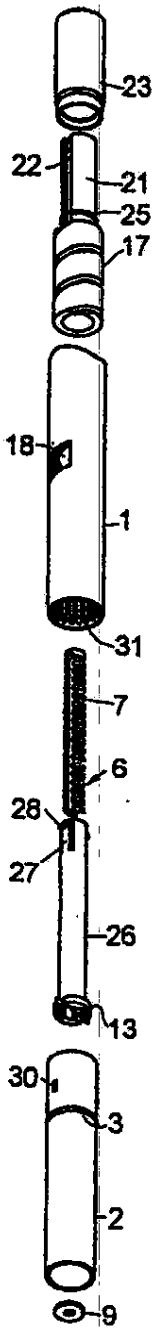


Fig.3

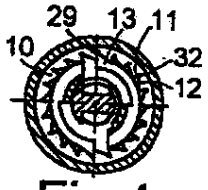


Fig.4

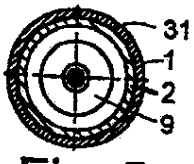


Fig. 5

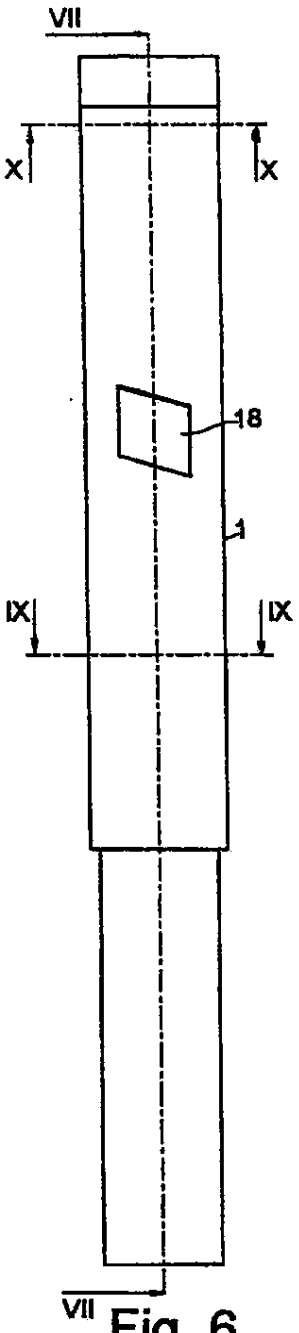


Fig. 6

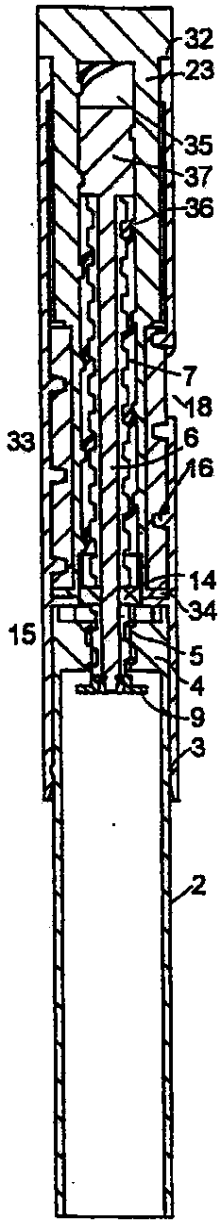


Fig. 7

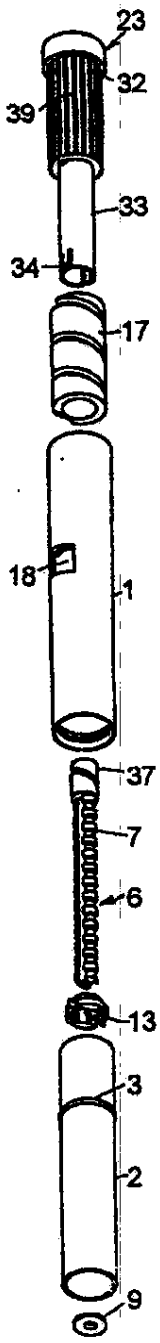


Fig.8

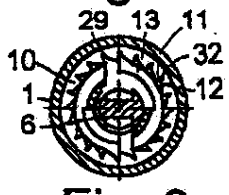


Fig. 9

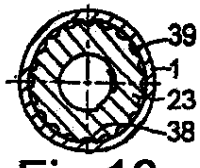


Fig.10

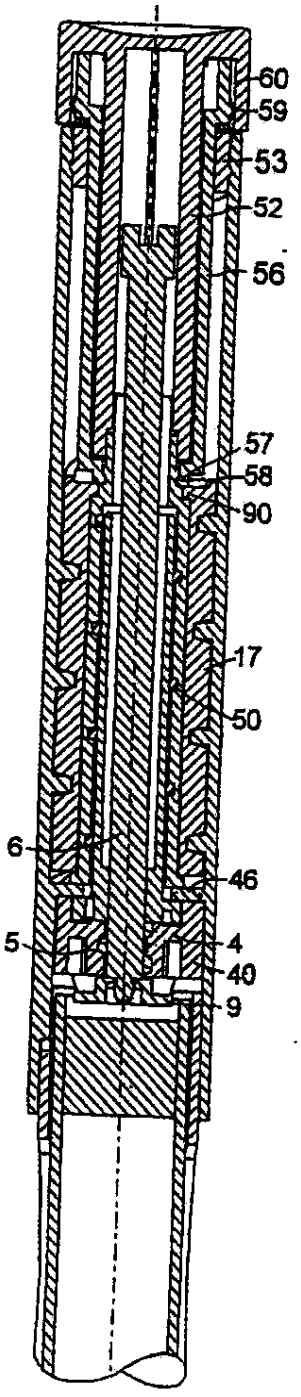


Fig. 11

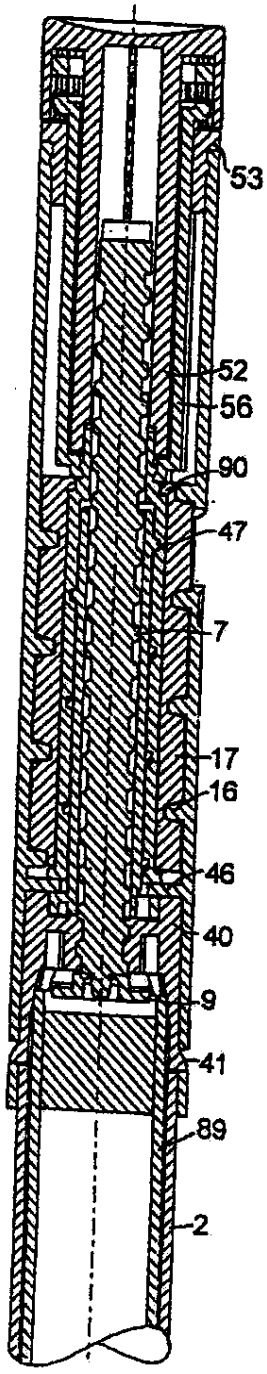


Fig. 12

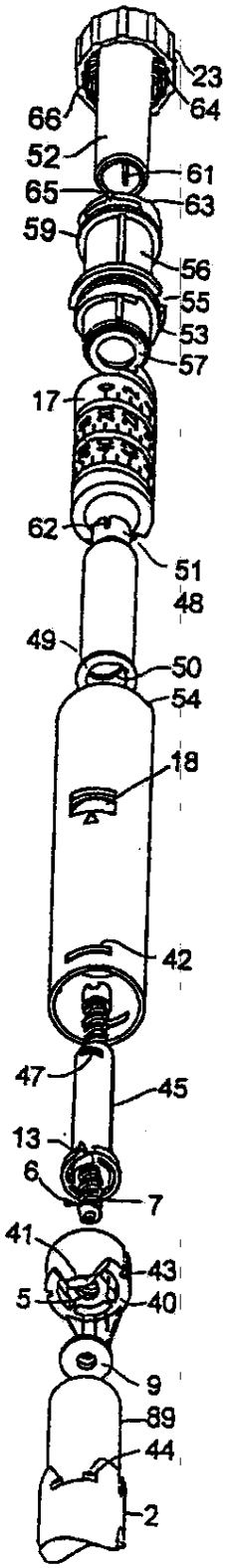


Fig. 13

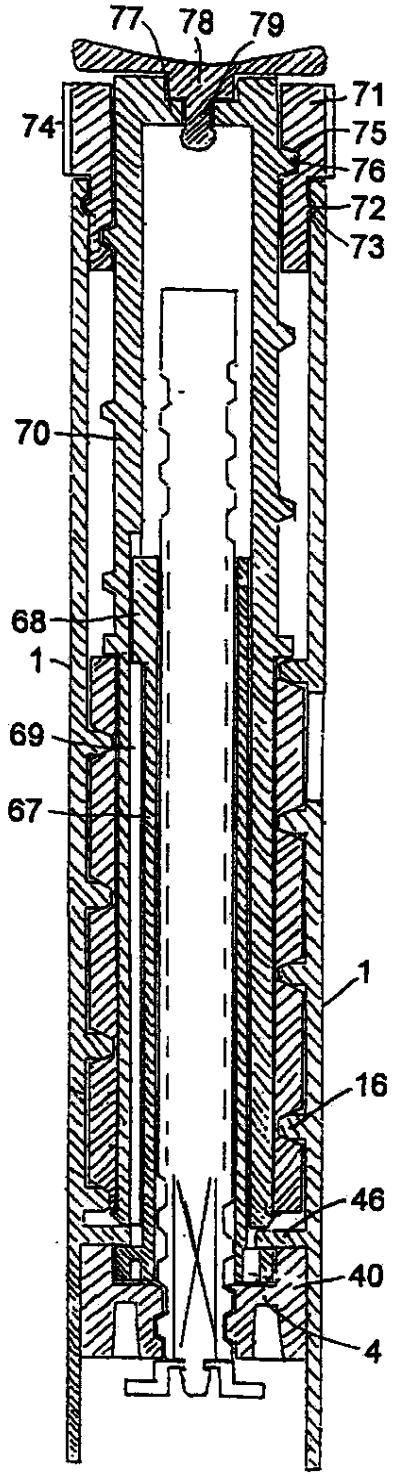


Fig. 14

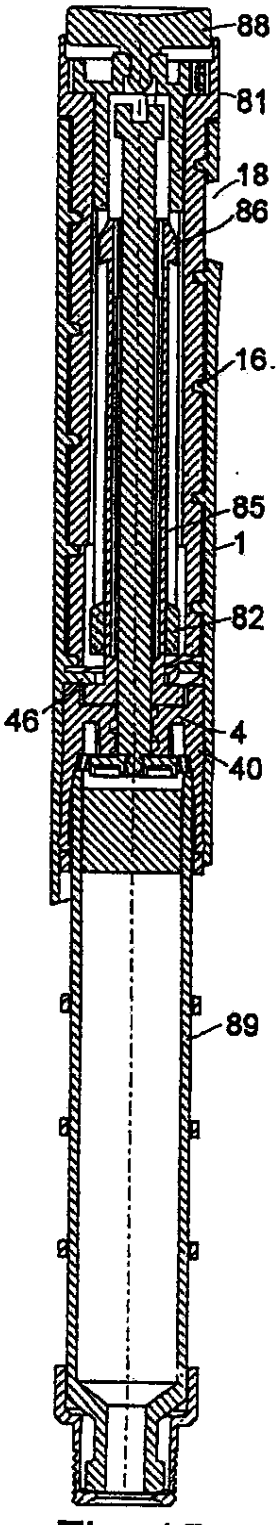


Fig. 15

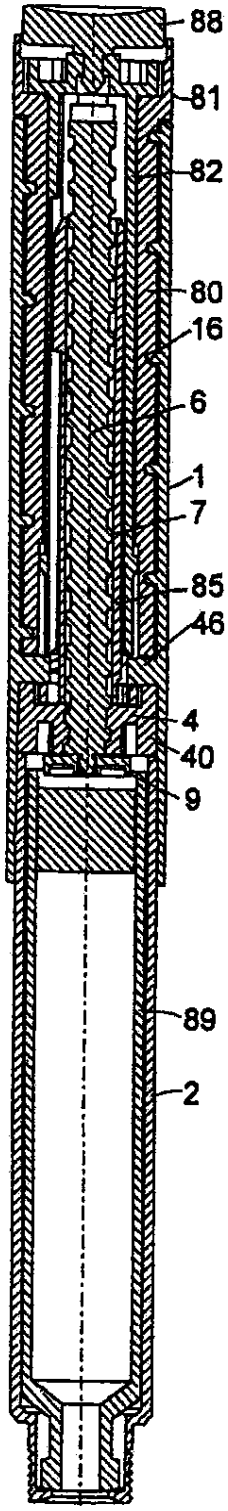


Fig.16

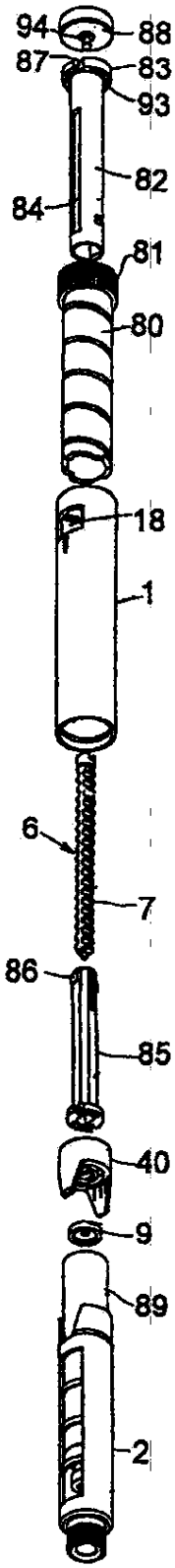


Fig. 17

INJECTION SYRINGE

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims priority under 35 U.S.C. 119 of Danish application PA 1998 00130 filed Jan. 30, 1998 and of U.S. provisional no. 60/073,820 filed Feb. 5, 1998, the contents of which are fully incorporated herein by reference.

The invention relates to injection syringes of the kind apportioning set doses of a medicine from a cartridge containing an amount of medicine sufficient for the preparation of a number of therapeutic doses.

Such syringes are mainly made for users who have to inject themselves frequently, e. g. diabetics. A number of demands are set to such syringes. The setting of a dose must be easy an unambiguous and it must be easy to read the set dose. It must be possible with a minimum of trouble to cancel or change a wrongly set dose and when the dose is injected the dose setting must return to zero. When a disposable syringe is in question, i.e. a syringe which is disposed of when the cartridge is empty, the syringe must further be cheap and made of materials suited for recycling or burning without producing noxious gases. For these purposes the number of parts from which the syringe is constructed and the number of different kinds of materials used in the syringe should be kept at a minimum.

Most dose setting devices work with a threaded piston rod co-operating with a nut where the nut and the piston rod may be rotated relative to each other. The dose setting may be obtained by screwing the nut away from a stop to which it is returned during the injection by pressing the piston rod until the nut member abuts the stop. By other dose setting devices one of the elements, the nut or the piston rod, is kept inrotatable and the other is allowed to rotate a set angle depending on the set dose, whereby the piston rod is screwed a distance through the nut.

In most syringes for apportioning set doses it is preferred that the piston rod is backing up the piston upon which it works during the injection. To obtain this precaution is taken to prevent the piston rod from moving in a proximal direction.

The syringe according to EP 327 910 is of the type wherein a nut is screwed away from a stop. During the setting of the dose the screwing may be performed in both direction so that a too large set dose may be lowered just by rotating the nut in an opposite direction. Means are provided preventing that negative doses are set. The mutual rotation of the piston rod and the nut is obtained by rotating a cap relative to the pen housing and a set dose may be read on a scale and a pointer provided at adjacent edges of the housing and the cap, these edges being so shaped that the cap can only be mounted firmly on the housing when the pointer points zero on the scale. It may be seen as a weak point that doses larger than the one obtained by rotating the parts 360° must be calculated by adding the number pointed at on the scale and a number printed on the side of a tubular extension of the nut which is moved out from the proximal end of the housing proportionally with the dose set and which tubular extension is closed at its proximal end to form an injection button.

In EP 450 905 the above drawback is overcome by writing the numbers along a helical line on a tubular extension of the nut so that these number may successively be seen in a window in a housing element enclosing said tubular extension. Hereby the size of the dose is indicated unambiguously but the user have to remember to set the dose setting device on zero before the next setting of a dose is performed. If this is forgotten a wrong dose may be set and the number may not be seen clearly in the window.

In EP 608 343 is described a pen having a dose setting mechanism wherein the dose is set by rotating a button relative to a housing to set a dose. By the rotation the button is screwed up from the end of the housing in a thread having a pitch so large that the thread connection is not self blocking, i. e. when the button is presses back to the end of the housing it will rotate back in the thread. The button is through a ratchet coupled to a driver, the ratchet forming a unidirectional coupling which during the rotation of the button in one direction to set a dose rides or clicks over the teeth of the ratchet. The cylindrical side of the button carries numbers which shows the size of the set dose in a window when the button is screwed outward. When the button is screwed back the unidirectional coupling will transmit the rotation to the driver which has a nut co-operating with a threaded piston rod which is made inrotatable in a housing . This thread connection has a pitch which makes the nut self locking on the piston rod. A set dose may be cancelled by drawing the engaging parts of the ratchet out of engagement against the force of a spring so that the rotation of the button is not transmitted to the driver and then press the button back to the housing . This pen fulfils all the objects mentioned only the dose cancelling procedure is a little troublesome as the dose set button cannot as it will come most naturally just be screwed back if a too large dose is set. Concomitantly forcing the coupling parts apart against the force of the spring and pressing or screwing the button back may be a little difficult and the demand for a spring necessitates use of metal parts in the syringe.

It is an object of the invention to provide a syringe which has the mentioned advantageous features without having the drawbacks known from existing syringes.

This is obtained by an injection syringes for apportioning set doses of a medicine from a cartridge containing an amount of medicine sufficient for the preparation of a number of therapeutic doses, comprising

- a housing
- a piston rod having a not circular cross-section and an outer thread
- a piston rod drive comprising two elements
  - a) a piston rod guide in relation to which the piston rod is axially displaceable but not rotatable, and
  - b) a nut member which is rotatable but not axially displaceable in the housing and which has an inner thread mating the thread of the piston rod to form a self locking thread connection,
- a dose setting mechanism comprising a not self locking thread connection along which an injection button by rotation of a dose setting element relative to said housing is screwed out from the proximal end of the housing to project from this proximal end a distance determined by the angle of said rotation and which thread connection by axial returning of the injection button transforms this axial movement to a rotation of one of the piston drive elements relative to the other,

which syringe according to the invention is characterised in that

- a unidirectional coupling is provided between the nut member and the piston rod guide allowing rotation of these parts relative to each other in one direction but not in the opposite direction, the allowed rotation being one by which the piston rod is transported in a distal direction in the syringe, the coupling being so designed

that a set initial reluctance has to be overcome before the rotation takes place.

During the setting of a dose a torque is exerted on the unidirectional coupling in the direction in which this coupling allows rotation after a set initial reluctance has been overcome. As this torque is a weak one resulting when the male and the female part of a not self locking thread connection is rotated relative to each other the initial reluctance can be made large enough to allow this rotation without causing any relative rotation of the parts in the coupling.

When the injection button is pressed the movement of this button is transformed into a rotation of the piston rod (or the nut member) relative to the nut member (or the piston rod). When the button is pressed hard enough the initial reluctans is overcome so that the two elements, the piston rod and the nut member, are rotated relative to each other.

According to the invention a click coupling providing an moderate resistance against rotation is established between the housing and the element rotated relative to the housing to set a dose. Hereby it is ensured that the position corresponding to a set dose is maintained and is not inadvertently altered. The clicks may be taken as an audible signal indicating the size of the set dose.

The unidirectional coupling may be a coupling comprising a pawl sliding over a pawl wheel with teeth having a steep front edge and a ramp shaped trailing edge, and the initial reluctance may be obtained by the fact that the trailing edges of the pawl wheel teeth has a depression engaged by a mating protrusion on the pawl.

A dose scale drum which has in its surface a helical track engaged by a helical rib on the inner side of the housing to form a not self locking thread connection between the housing and the drum may be coupled to the injection button to be moved axially with this button. This way the dose scale drum will be rotated relative to the housing when it is axially displaced with the injection button in said housing.

The thread connection by which the injection button is screwed out from the housing by setting a dose may be the thread connection between the dose scale drum and the housing. In this case the dose scale drum must be coupled to a driver rotating the piston rod (or the nut member) relative to the nut member (or the piston rod) when the injection button is pressed.

A dose is set by rotating an element relative to the housing, and this element may be an element carrying the nut member and the unidirectional coupling so that the rotation is transmitted through said unidirectional coupling to the dose setting drum. The rotation transmitted is in the direction in which the coupling can run free when an initial reluctance is overcome. However, the force needed to screw the dose scale drum up along its thread is not large enough to overcome said reluctance and consequently the rotation is transmitted through the coupling.

In one embodiment of the syringe according to the invention the element rotated relative to the housing may be a part carrying the nut member and the unidirectional coupling through which the rotation is transmitted to the dose setting drum.

In another embodiment of the syringe according to the invention the element rotated relative to the housing may be the injection button and the not self locking thread connection which determines the lifting of the injection button may be an inner thread in a bore in the injection button engaging an outer thread on an enlargement of the piston rod. When the injection button is screwed up along the piston rod to project from the housing a torque is exerted on the piston rod trying to rotate this piston rod in a direction which will move it in a distal direction in the syringe. Such a rotation is just the rotation which is allowed by the unidirectional coupling which blocks rotation in the opposite direction. Due to the initial reluctance against rotation of the coupling parts relative to each other the piston rod will not be rotated when the injection button is screwed up along it in a proximal direction in the syringe. If the injection button is screwed in the opposite direction the unidirectional coupling will definitively block a relative rotation of the piston rod and the nut member in the direction which would draw the piston rod in a proximal direction.

In the last mentioned embodiment of the injection syringe the dose scale drum may b e mounted rotateable but not axially displaceable on the injection button. When the dose scale drum is moved with the injection button in the axial direction of the syringe the drum will be rotated due to the not self locking thread connection between said drum and the housing so that a number on the drum corresponding to the set dose is visible in a window provided in the wall of the housing. In this embodiment the pitch of the dose drum thread need not be identical with the pitch of the thread along which the injection button is screwed to set a dose, only both thread connections must have a pitch large enough to make the thread connection the not self locking type, i.e. of the type by which an axial movement can be transformed into a rotation.

In an appropriate embodiment of the syringe according to the invention the dose scale drum is mounted rotatable but not axially displaceable on the injection button.

During the injection the injection button must be kept inrotatable but axially displaceable relative to the housing in the angular position to which the injection button is rotated during the setting of a dose. This may be obtained by letting the click coupling between the housing and the injection button comprise protrusions on one part engaging axial grooves in the other. When the injection button is pressed home into the housing the internal thread in the bore of this button will act on the engaging outer thread on the enlargement at the end of the piston rod and convert the axial movement of the injection button to a rotational movement of the piston rod in a direction by which the piston rod is screwed through the nut member in a distal direction in the syringe. The piston rod guide which is connected to one part of the unidirectional coupling is allowed to rotate when the initial reluctance against rotation in the direction else allowed by the coupling is overcome. Also a rotational movement of the dose scale drum is induced by the axial movement of the injection button so that the scale is returned to its zero position when the button is pressed home. When rotation of the dose scale drum and the piston rod is induced by the axial movement of the injection button this button is reacted upon by a torque which must be taken up by the click connection between the injection button and the housing which connection must consequently be strong enough to absorb this force without rotating.

In the following the invention is described in further details with references to the drawing, wherein

FIG. 1 shows a front view of an embodiment of an injection syringe according to the invention,

FIG. 2 shows a sectional view along the line II—II in FIG. 1,

FIG. 3 shows in a reduced scale an exploded view of the syringe in FIG. 1,

FIG. 4 shows a sectional view along the line IV—IV in FIG. 1,

FIG. 5 shows a sectional view along the line V—V in FIG. 1,

FIG. 6 shows a front view of another embodiment of an syringe according to the invention,

FIG. 7 shows a sectional view along the line VII—VII in FIG. 6,

FIG. 8 shows in a reduced scale an exploded view of the syringe in FIG. 6,

FIG. 9 shows a sectional view along the line IX—IX in FIG. 6,

FIG. 10 shows a sectional view along the line X—X in FIG. 6.

FIG. 11 shows a sectional side view of another embodiment of a syringe according to the invention,

FIG. 12 shows a sectional side view perpendicular to the view in FIG. 11,

FIG. 13 shows in a reduced scale an exploded view of the syringe in FIGS. 11 and 12,

FIG. 14 shows a sectional side view of the dose setting part of another embodiment of a syringe according to the invention,

FIG. 15 shows a sectional side view of still another embodiment of a syringe according to the invention,

FIG. 16 shows a sectional side view perpendicular to the view in FIG. 15,

FIG. 17 shows in a reduced scale an exploded view of the syringe in FIGS. 15 and 16,

Initially it may be convenient to define that in this application directions of rotation are always seen from the proximal end of the pen and designed as clockwise or anticlockwise seen in this direction.

FIG. 1 shows an injection syringe of the kind by which a liquid from an ampoule can be apportioned in a number of individually set does. FIG. 3 shows an exploded view of this syringe and the FIGS. 2, 4 and 5 sectional views taken along different lines in FIG. 1.

The syringe comprise a tubular housing 1 which is by a partition 15 divided into a first and a second division into the first one of which an ampoule holder 2 is snapped by a snap lock comprising a ring shaped bead 3 on the ampoule holder 2 which bead is snapped into a corresponding circumferantial grove in the inner wall of the housing 1 near an open end thereof. By this snap connection the ampoule holder 2 is secured in the housing 1 so that it can be rotated but not axially displaced relative to this housing.

In the syringe ready for use an ampoule is mounted in the ampoule holder which is then at its distal end closed by an end wall provided with a needle hub receiving part onto which a needle hub can be mounted having a needle with one end communicating with the content of the ampoule and the other end free to be inserted into a patient. In the shown syringe, however, neither ampoule, end wall nor needle hub are shown.

The end of the ampoule holder 2 inserted in the housing 1 is closed by a wall 4 having a central bore with an internal thread 5. A piston rod 6 having an external thread 7 mating the thread 5 of said bore extends through said bore. The threads are so designed that a clockwise rotation of the piston rod will drive this rod into an ampoule accommodating compartment 8 in the first division of the housing 1. At its end projecting into the compartment 8 the piston rod 6 is provided with a pressure foot 9 designed to abut a piston closing the rear end of an ampoule accommodated in the ampoule holder 2.

In the proximal side of the end wall 4 the bore is enlarged and the internal side of the enlargement is provided with pawl wheel teeth 10 having a steep front edge 11 facing the clockwise direction and a ramp shaped rear edge 12 facing the anticlockwise direction. At least one pawl 13 mounted on a piston rod guide 14 co-operates with the pawl teeth 10 so that said piston rod guide can only be rotated clockwise in the ampoule holder 2.

On the inner wall of the second division of the housing 1 a helical protruding rib 16 is provided defining an inner thread with a high pitch. A dose scale drum 17 is in its outer wall provided with a helical grove defining a corresponding external thread mating the inner thread just mentioned. The pitch angle of the threads exceeds the angle of friction for the materials forming the parts of the thread connection and consequently the thread connection is of the not self locking type which induce a relative rotation of the parts of the connection when these part are moved axially relative to each other.

Numbers indicating set doses are printed on the outer wall of the dose drum 17 and the number corresponding to a set dose is shown in a window 18 provided in the side wall of the housing 1.

The dose scale drum 17 is provide with a tubular extension 21 having an end near the proximal end of the syringe. Said end of the extension is closed by an end wall 19 having a central outer protrusion 20. In a part of the wall adjacent to the end wall 19 the extension 21 is provided with slots 22. The said end of the extension is covered by a cup shaped cap 23 forming an injection button. Internal hooks 24 at the open end of this cap snaps over an external circumferential bead 25 on the extension 21 and the protrusion 20 on the end wall 19 abuts the inner side of the bottom of the cap 23 to form a journal about which the injection button can rotate relative to the extension 21 whereas it cannot be axially displaced relative to this extension.

A driver tube 26 integral with the piston rod guide 14 extends from this piston rod guide to the end wall 19 of the dose scale drum extension 21 and is at its proximal end divided into tongues 27 terminated by external hooks 28 engaging the slots 22 in the extension 21. This way the dose scale drum 17 is bound to rotate with the driver tube 26 but is axially displaceable relative to this tube.

To set a dose the ampoule holder 2 is rotated anticlockwise in the first division of the housing 1. This rotation is performed against a resistance presented due to the fact that a protrusion 30 on the outer wall of the ampoule holder rests in one of a number of depressions 31 circumferentially provided in the inner wall of said first division of the housing as shown in the cross-sectional view in FIG. 3. The angular spacing of the depressions are appropriately made so that a dose of one unit is set when the protrusion is moved from one depression to the neighbouring depression so that the number of clicks heard and felt during the dose setting rotation corresponds to the size of the set dose.

The rotation of the ampoule holder is due to the friction in the engaging threads 5 and 7 transmitted to the piston rod 6 and further through the unidirectional coupling to the piston rod guide 14 although the torque is transmitted in a such a direction that the pawl will intend to click over the pawl wheel teeth 10. However, before this click function is performed a reluctance have to be overcome. This reluctance is obtained by providing the pawl 13 with a protrusion 29 at its end engaging the pawl wheel teeth 10 and by providing depressions 32 in the ramp shaped edges 12 of the pawl wheel teeth into which depressions the protrusion 29 on the pawl 13 will rest. Before the clicking release of the coupling is obtained a torque sufficient to lift up the protrusion 29 of the pawl 13 from the depression 32 in the ramp shaped edge 12 must be provided. Altogether a moderate torque can be transmitted from the rotated ampoule holder 2 to the driver tube 26. As the hooks 28 at the proximal end of the driver

tube 26 engage the slots 22 in the dose scale drum extension 21 the dose scale drum will be rotated and be screwed upwards in the second division of the housing 1 and the injection button 23 will be lifted to protrude from the proximal end of the housing 1. As only a small torque is needed to screw up the dose scale drum this is obtained without releasing the unidirectional coupling to its clicking release function mode. The size of the set dose can currently be seen on the part of the dose scale drum which is presented in the window 18. If a too large dose has been set the ampoule holder can be rotated in a clockwise direction until the number corresponding to the size of the wanted doe is presented in the window 18.

To inject the set dose the injection button 23 is pressed home into the housing 1. Thereby the dose scale drum 17 is pressed in the distal direction and due to the thread connection between said drum and the housing 1 a torque is exerted on the drum rotating this drum in a clockwise direction. Said torque is via the slots 22 in the drum extension 21 and the hooks 28 at the end of the driver tube 26 and this tube itself transmitted to the piston rod guide 14. The pawls 13 on the piston rod guide are allowed to rotate in the clockwise direction when the torque is strong enough to overcome the reluctance provided by the protrusions 29 on the pawls engaging the depressions 32 in the ramp shaped edges of the pawl wheel teeth.

Such a strong torque is provided if only the inject button 23 is pressed hard enough. The piston rod guide 14 will now rotate clockwise with the unidirectional coupling working in its clicking released mode and the piston rod will be rotated clockwise too and will thereby be screwed through the wall 4 further into the ampoule accommodating compartment 8. The unidirectional coupling will never allow an anticlockwise rotation of the piston rod guide and the piston and this way it is ensured that the pressure foot 9 will never be drawn out of abutment with the piston in a not shown ampoule in the compartment 8.

In the shown embodiment the end wall 4 with its threaded bore forms a nut member relative to which the piston rod is rotated by the piston rod guide 14 and the driver tube 26. Embodiments may be imagined wherein the piston rod guide is provided in the wall 4 and a nut element is rotated by the driver tube and such embodiment will not be beyond the scope of the invention.

Another embodiment is described with reference to the FIGS. 6–10. Elements corresponding to elements in the embodiment described with references to the FIGS. 1–5 are provided with the same reference numbers. Different from the embodiment in FIGS. 1–5 is the fact that the injection button 23 and not the dose scale drum 17 is provided with an extension 33, and that the driver tube 26 is omitted. Further the injection button 23 is provided with a flange 32 which abuts the end of the housing when the injection button is pressed home. The extension 33 serves as a journal for the dose scale drum 17 which is free to rotate on this journal but bound to follow axial movements of the injection button 23 due to hooks 34 at the end of the extension 33. A longitudinal bore 35 in the injection button and its extension 33 is provided with an internal helical rib 36 engaging a corresponding helical groove in an enlargement 37 at the proximal end of the piston rod to form a thread connection between said button 23 and said piston rod 6. The pitch of this thread connection is so that a not self locking thread connection is formed.

To set a dose the injection button 23 is manually rotated in a clockwise direction. Thereby this button is screwed outwards from the housing 1 as the piston rod 6 will through the piston rod guide 14 and the unidirectional coupling be kept inrotatable although said unidirectional coupling in influenced by a torque in its release direction, however, due to the provided initial reluctance the piston rod guide 14 will not immediately be rotatable. In its movement outwards the injection button 23 will draw the dose scale drum 17 with it. When this drum is moved axially in the housing it will be rotated due to the not self locking thread connection between said drum 17 and the housing 1.

By this construction the thread along which the injection button is screwed outwards and the tread along which the dose scale drum is rotated in the housing may be different.

A click connection corresponding to the one established between the cartridge holder 2 and the housing 1 in the embodiment according to FIG. 1 is in the embodiment according to FIG. 6 appropriately provided between the injection button 23 and the housing 1 where one or more protrusions 38 provided on the inner wall of the housing engages grooves 39 in a cylindrical outer wall of the button 23. Thereby axial movement of the injection button is allowed in all its possible angular positions.

When the injection button is pressed to inject a set dose said button will be maintained inrotatable during its axial movement as the locking between the above mentioned protrusions on the inner wall of the housing and grooves on the outer wall of the button is strong enough to absorb the torque exerted on the injection button when it drives the piston rod to rotation in a clockwise direction after having overcome the reluctance against rotation in the release direction of the unidirectional coupling.

The embodiment shown in FIGS. 11, 12 and 13 has the housing 1 with the window 18. The end wall 4 with the internal thread 5 is provided in a separate member 40 which is mounted in an end of the housing, the member 40 having protrusions 41 engaging slots 42 in the housing to lock the member 40 to the housing 1. Further the member 40 has at its periphery longitudinal recesses 43 which are engaged by not shown internal ribs in the housing to lock the member 40 against rotation relative to the housing 1. Further protrusions 44 on the ampoule holder 2 engage the slots 42 to lock the ampoule holder 2 to the housing 1.

The piston rod 6 engages by its external thread 7 the internal thread of the end wall 4 and is at its end in the ampoule holder terminated by a pressure foot 9 relative to which the piston rod 6 is rotatable. A driver tube 45 is at one end provided with the pawl 13 which engages pawl wheel teeth in the member 40 and is held between a ring shaped wall 46 in the housing and the end wall 4 in the member 40 to keep the driver tube 45 from axial movement but allowing it to rotate. On its inner wall the driver tube 45 has a key engaging a longitudinal recess in the piston rod 6. Thereby rotation of the driver tube is transmitted to the piston rod 6 whereas the piston rod can move freely in the axial direction of the driver tube 45. On its outer wall the driver tube 45 has an outer thread 47 which engages an inner thread 50 in a nut member 48 which has at its distal end a flange 49 and is at its proximal end provided with a part 51 with reduced diameter to which part one end of a tubular part 52 which at its other end carries a button 23 is secured.

In the proximal end of the housing 1 a bushing 53 is secured to be non rotatable an non displaceable relative to said housing 1 the rotational locking being obtained by lugs 54 at the proximal end of the housing engaging recesses 55 at the periphery of the bushing 53. A guide member 56 is longitudinally displaceable in the bushing 53 but inrotatable relative to said bushing and consequently relative to the housing 1. The guide member has at its distal end an annular

end wall **57**. The part **51** of the nut member **48** is passed through the opening of said end wall **57** and has a bead **58** gripping into a circumferential inner recess in the wall of annular opening through said end wall to keep the bushing **53** secured to said part **51** so that this part can be rotated but not axially displaced in relation to the bushing **53**. The scale drum **17** is journalled on the nut member **48** and is held on this nut member by having a flange **90** held between the end wall **57** of the guide member **56** and the shoulder formed where the part **51** connects to the nut member **48**.

The button **23** is held rotatably on the guide member **56** which has a ring bead **59** engaging a circumferential recess **60** in the inner wall of the button **23** which recess **60** is somewhat broader than than the bead **59** so that the button in excess of being rotatable on said bushing **53** can be axially displaced a distance defined by the width of the recess **60** relative to the width of the bead **59**. The button **23** is coupled to the nut member **48** by internal ribs **61** in the tubular part **52** engaging slots **62** in the proximal part of the part **51** of the nut member **48**. This coupling forces the button **23** and the nut member **48** to follow each other in rotational movements but allow a minor relative axial displacement.

The proximal end surface of the guide member **56** has one or more axially directed protrusions **63** which can co-operate with radial recesses **64** in the bottom of the button **23**, but mainly a biasing keeps these recesses and protrusions out of engagement. Further the guide member has at its proximal end at least one radial protrusion **65** which is biased to engage axial recesses **66** in an inner wall of the button to produced a click sound each time the button is rotated relative to the bushing so that the protrusion jump from one recess to the neighbour recess.

To set a dose the button **23** is rotated in a clockwise direction. This rotation is due to the coupling between the ribs **61** and the slots **62** transmitted to the nut member **48** which is then screwed in distal direction along the driver tube **45** which is held inrotatably in the housing due to the reluctans of the pawl **13** to move along the pawl teeth in the member **40**. The movement of the nut member **48** in proximal direction makes the scale drum **17**, the guide member **56**, and the tubular part **52** with the button move in proximal direction so that the button is elevated over the end proximal end of the housing **1**. A to high set dose can be reduced by rotating the button in an anti clockwise direction.

During the rotation of the button the radial protrusion **65** of the guide member **56** clicks from one axial recess **66** to the other. The distance between can appropriately be chosen so that a click corresponds to a changing of the set dose by one international unit up or down. Due to engagement between the helical grove on the cylinder wall of the scale drum and a helical rib on the inner wall of the housing the movement of the dose scale drum **17** will rotate and displace said drum so that the set dose is shown in the window **18**.

When the dose scale drum is displaced outwardly in the housing a steep front side of a saw tooth **91** at the proximal end of the dose scale drum **18** will abut a steep front side of a similar tooth **92** on the bushing whereby the rotation of the dose scale drum is stopped to indicate that a maximum dose has been set.

To inject the set dose the button **23** is pressed. Thereby the bias keeping the protrusions **63** and the recesses **64** out of engagement is overcome and the said engagement is established. The button **23** is now locked relative to the guide element **56** which is again locked against rotation relative to the bushing **53** and consequently relative to the housing **1**. The coupling between the tubular part **52** and the nut member **48** makes this nut member inrotatable relative to the housing so an axial movement of said nut member in a distal direction will due to the not self locking thread coupling between this nut element and the driver tube **45** make this driver tube **45** rotate in a clockwise direction and due to the key/groove coupling between the driver tube **45** and the piston rod **6** said piston rod will be screwed through the end wall **4** further into the ampoule holder compartment. The locking of the button **23** against rotation during the injection ensures that the set dose is not inadvertently changed during the injection.

In the embodiment shown in FIG. **14** separate buttons are provided for the dose setting and the injection. Corresponding to previously described embodiments this one has a housing **1** and a driver tube **67** which is rotatable in only one direction due to a pawl which engage pawl wheel teeth in a part secured in the distal end of the housing. Trapping of the pawl between the member **40** and a ring shaped wall **46** in the housing fixes the driver tube against axial movement. On the outer wall of the driver tube **67** an axial rib **68** is provided which rib engages an axial recess **69** in a tubular injection element **70** to transmit rotation of said injection element to the driver tube **67**.

At the proximal end of the housing **1** a dose setting button **71** is mounted so that this button can be rotated but not axially displaced relative to the housing **1**. This is obtained by the fact that the dose setting button **71** on a part fitting into the housing has a ring shaped bead **72** which engages a mating circumferential recess **73** in the inner wall of the housing. Outside the housing the dose setting button has a part having a diameter corresponding to or being larger than the diameter of said housing which part can be provided with axial ribs **74** to ensure a good grip by the setting of a dose. The dose setting button **71** has a central bore the inner wall of which has a helical recess **75** engaging a helical rib **76** provided on the outer wall of the proximal part of the injection element **70** which element passes through the bore of the dose setting button **71**. The outer wall of the distal part of the injection element **70** forms a journal for the scale drum **17** which through an outer helical recess engaged by an internal helical rib **16** in the housing is rotated to show the set dose in the window **18** when the scale drum is displaced axially in the housing. The proximal end of the injection member is terminated by an end wall **77** which carries an injection button **78** which is by a pivot pin **79** journaled in a central bore in said end wall **77**.

To set a dose the dose setting button **71** is rotated in a clockwise direction. As the injection member is kept non rotatable by its coupling to the driver tube **67** the collaboration between the helical recess **75** in the inner wall of the dose setting button **71** and the helical rib **76** on the outer wall of the injection element **70** will screw the injection element out through the dose setting button so that the injection button **78** is lifted up from the proximal end of the housing. Although the driver tube **67** with its pawl can be rotated in the clockwise direction an initial torque is needed which is larger than the torque transmitted from the dose setting button to the injection element.

To inject a set dose the injection button **78** is pressed and the injection element is moved back into the housing. The co-operation of the helical recess **75** in the inner wall of the dose setting button **71** and the helical rib **76** on the outer wall of the injection element **70** will now make the injection element rotate in a clockwise direction and if only the injection button is pressed hard enough a torque is produced large enough to overcome the initial reluctance of the pawl mechanism against rotation in said clockwise direction.

The separation of the dose setting button **71** and the injection button **78** makes it less likely that the dose setting button is inadvertently operated during the injection.

FIGS. 15, 16 and 17 illustrates still another embodiment. To maintain a clockwise rotation of a dose setting button for increasing the set dose the pawl mechanism working between the driver tube and the housing is turned so that it bars clockwise rotation and reluctantly allows anticlockwise rotation of the driver tube. Further the thread of the piston rod and the thread in the end wall of the housing is so designed that an anticlockwise rotation of the piston will screw the piston rod through said end wall and into the cartridge holder compartment. The piston rod has a not round cross-section and fits through the driver tube bore which has a corresponding not round cross-section. This way rotation is transmitted whereas the piston rod is allowed to move longitudinally through the driver tube.

A scale drum **80** is in its outer wall provided with a helical track which is engaged by a helical rib **16** along the inner wall of the housing **1**. At its proximal end the scale drum **80** has a diameter exceeding the inner diameter of the housing to form a dose setting button **81** which on its cylindrical outer wall is knurled to ensure a good finger grip.

A bushing **82** having a flange **83** at its proximal end and having a pair of opposite longitudinal slots **84** through its side walls fits into the scale drum **80** and over the driver tube **85** which tube has on its outer wall hooks **86** engaging the slots **84** of the bushing **82** whereby the bushing **82** and the driver tube **85** is coupled to each other so that rotation but not longitudinal displacement is transmitted between said two elements.

In the dose setting button a compartment is provided having a cylindrical side wall circumferentially provided with longitudinal recesses and a bottom with a rosette of teeth having a triangular cross-section. The flange **83** of the bushing **82** is adopted in said compartment and has at its periphery a radial protrusion **87** which is biased toward the side wall of the compartment. At its distal side the flange **83** has a rosette **93** of teeth which can be brought into engagement with the rosette at the bottom of the compartment.

The bushing **82** is mounted in the scale drum **80** with protrusion on the outer wall of the bushing **82** engaging recesses in the inner wall of the scale drum **80** so that a limited movement of the bushing in the scale drum is allowed so that the bushing can be moved axially relative to the scale drum to make or not make the teeth of said rosettes engage each other. An injection button **88** is rotatably mounted with a pivot pin **94** journaled in an end wall of the bushing **82**.

When a dose is set by rotating the dose setting button **81** in a clockwise direction, the scale drum is screwed out of the housing and the dose setting button is lifted away from the proximal end of the housing. The bushing is kept non rotated due to its coupling to the driver tube which is locked against clockwise rotation and if a set dose is reduced by rotating the dose setting button **81** in an anticlockwise direction the pawl mechanism working between the driver tube and the housing is sufficient reluctant to rotate in its not blocking direction to prevent the bushing **82** from following this anticlockwise rotation. Therefore by the rotation of the dose setting button **81** in any direction the radial protrusion **87** on the flange **83** of the bushing **82** will click from one of the axial recess in the inner wall of the dose setting button **81** to the next one, the recesses being so spaced that one click corresponds to a chosen change of the set dose, e. g. one unit or a half unit. During the setting the rosette in the dose setting button forces the rosette **93** on the flange **83** of the bushing **82** out of engagement.

When the injection button **88** is pressed to inject the set dose the said rosettes are pressed into engagement so that the bushing **82** will follow the anticlockwise rotation of the dose setting button **81** which is induced by the thread engagement between the helical track of the scale drum **80** and the rib **16** in the housing when the scale drum **80** is pressed back into said housing. The bushing will rotate the driver tube **85** in an anticlockwise direction which the pawl mechanism reluctantly allows an the piston rod is thereby screwed further into an ampoule **89** in the ampoule holder **2**.

By this device the risk for inadvertent operation of the dose setting button **81** during the injection is eliminated. Further the device consist of a minimum of parts whereby the manufacturing is made easy.

We claim:

1. An injection syringe for apportioning set doses of a medicine from a cartridge containing an amount of medicine sufficient for the preparation of a number of therapeutic doses, comprising

a housing;

a piston rod having a not circular cross-section and an outer thread

a piston rod drive comprising two elements

a) a piston rod guide mating the not circular cross-section of the piston rod to allow axially displacement but not rotatation of the piston rod in relation to said piston rod guide, and

b) a nut member which is not axially displaceable in the housing and which has an inner thread mating the thread of the piston rod to form a self locking thread connection,

a dose setting mechanism comprising a not self locking thread connection along which an injection button by rotation of a dose setting element relative to said housing is screwed out from the proximal end of the housing to project from this proximal end a distance determined by the angle of said rotation and which thread connection by axial returning of the injection button transforms this axial movement to a rotation of one of the piston drive elements relative to the other, characterised in that a unidirectional coupling is provided between the nut member and the piston rod guide allowing rotation of these parts relative to each other in one direction but not in the opposite direction, the allowed rotation being one by which the piston rod is transported in a distal direction in the syringe, the coupling being so designed that an initial reluctance set large enough to resist a torque exerted on the coupling by the dose setting has to be overcome before rotation takes place.

2. An injection syringe according to claim 1, characterised in that a click coupling providing an moderate resistance against rotation in either directions is established between the housing and the element rotated relative to this housing to set a dose.

3. An injection syringe according to claim 1, characterised in that the unidirectional coupling comprises a pawl sliding over a pawl wheel with teeth having a steep front edge and a ramp shaped trailing edge.

4. An injection syringe according to claim 3, characterised in that the trailing edges of the pawl wheel teeth has a depression engaged by a mating protrusion on the pawl.

5. An injection syringe according to claim 1, characterised in that a dose scale drum has in its surface a helical track engaged by a helical rib on the inner side of the housing to form a not self locking thread connection between the housing, and that the dose scale drum and is coupled to the injection button to be moved axially with this button.

6. An injection syringe according to claim 5, characterised in that the thread connection by which the injection button is lifted by setting a dose is the thread connection between the dose scale drum and the housing.

7. An injection syringe according to claim 1, characterised in that the element rotated relative to the housing is the injection button and that the not self locking thread connection which determines the lifting of the injection button is an inner thread in a bore in the injection button engaging an outer thread on a part with enlarged diameter of the piston rod.

8. An injection syringe according to claim 1, characterised in that the piston rod guide is mounted in a driver tube in which tube the piston rod is axially displaceable but is rotated with said tube, and that the not self locking thread connection which determines the lifting of the injection button is provided between the driver tube and a part which is axially displaceable with the injection button.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 6,004,297
DATED : December 21, 1999
INVENTOR(S) : Steenfeldt-Jensen et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 12,
Line 23, please delete "rotation", and insert -- rotation --.

Signed and Sealed this

Twenty-seventh Day of November, 2001

Attest:

Nicholas P. Godici

Attesting Officer

NICHOLAS P. GODICI
Acting Director of the United States Patent and Trademark Office

PATENT APPLICATION SERIAL NO. _____

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE
FEE RECORD SHEET

02/04/1999 TMBE1 00000015 141447 09238849
01 FC:101 760.00 CH

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An injection syringe

The invention relates to injection syringes of the kind apportioning set doses of a medicine from a cartridge containing an amount of medicine sufficient for the preparation of a number of therapeutic doses.

Such syringes are mainly made for users who have to inject themselves frequently, e. g. diabetics. A number of demands are set to such syringes. The setting of a dose must be easy an unambiguous and it must be easy to read the set dose. It must be possible with a minimum of trouble to cancel or change a wrongly set dose and when the dose is injected the dose setting must return to zero. When a disposable syringe is in question, i.e. a syringe which is disposed of when the cartridge is empty, the syringe must further be cheap and made of materials suited for recycling or burning without producing noxious gases. For these purposes the number of parts from which the syringe is constructed and the number of different kinds of materials used in the syringe should be kept at a minimum.

Most dose setting devices work with a threaded piston rod co-operating with a nut where the nut and the piston rod may be rotated relative to each other. The dose setting may be obtained by screwing the nut away from a stop to which it is returned during the injection by pressing the piston rod until the nut member abuts the stop. By other dose setting devices one of the elements, the nut or the piston rod, is kept inrotatable and the other is allowed to rotate a set angle depending on the set dose, whereby the piston rod is screwed a distance through the nut.

In most syringes for apportioning set doses it is preferred that the piston rod is backing up the piston upon which it works during the injection. To obtain this precaution is taken to prevent the piston rod from moving in a proximal direction.

The syringe according to EP 327 910 is of the type wherein a nut is screwed away from a stop. During the setting of the dose the screwing may be performed in both direction so that a too large set dose may be lowered just by rotating the nut in an opposite direction. Means are provided preventing that negative doses are set. The mutual rotation of the piston rod and the nut is obtained by rotating a cap relative to the pen housing and a set dose may be

read on a scale and a pointer provided at adjacent edges of the housing and the cap, these edges being so shaped that the cap can only be mounted firmly on the housing when the pointer points zero on the scale. It may be seen as a weak point that doses larger than the one obtained by rotating the parts 360° must be calculated by adding the number pointed at on the scale and a number printed on the side of a tubular extension of the nut which is moved out from the proximal end of the housing proportionally with the dose set and which tubular extension is closed at its proximal end to form an injection button.

In EP 450 905 the above drawback is overcome by writing the numbers along a helical line on a tubular extension of the nut so that these number may successively be seen in a window in a housing element enclosing said tubular extension. Hereby the size of the dose is indicated unambiguously but the user have to remember to set the dose setting device on zero before the next setting of a dose is performed, If this is forgotten a wrong dose may be set and the number may not be seen clearly in the window.

In EP 608 343 is described a pen having a dose setting mechanism wherein the dose is set by rotating a button relative to a housing to set a dose. By the rotation the button is screwed up from the end of the housing in a thread having a pitch so large that the thread connection is not self blocking, i. e. when the button is presses back to the end of the housing it will rotate back in the thread. The button is through a ratchet coupled to a driver, the ratchet forming a unidirectional coupling which during the rotation of the button in one direction to set a dose rides or clicks over the teeth of the ratchet. The cylindrical side of the button carries numbers which shows the size of the set dose in a window when the button is screwed outward. When the button is screwed back the unidirectional coupling will transmit the rotation to the driver which has a nut co-operating with a threaded piston rod which is made inrotatable in a housing . This thread connection has a pitch which makes the nut self locking on the piston rod. A set dose may be cancelled by drawing the engaging parts of the ratchet out of engagement against the force of a spring so that the rotation of the button is not transmitted to the driver and then press the button back to the housing . This pen fulfils all the objects mentioned only the dose cancelling procedure is a little troublesome as the dose set button cannot as it will come most naturally just be screwed back if a too large dose is set. Concomitantly forcing the coupling parts apart against the force of the spring and pressing or screwing the button back may be a little difficult and the demand for a spring necessitates use of metal parts in the syringe.

It is an object of the invention to provide a syringe which has the mentioned advantageous features without having the drawbacks known from existing syringes.

This is obtained by an injection syringes for apportioning set doses of a medicine from a cartridge containing an amount of medicine sufficient for the preparation of a number of therapeutic doses, comprising

a housing

a piston rod having a not circular cross-section and an outer thread

a piston rod drive comprising two elements

a) a piston rod guide in relation to which the piston rod is axially displaceable but not rotatable, and

b) a nut member which is rotatable but not axially displaceable in the housing and which has an inner thread mating the thread of the piston rod to form a self locking thread connection,

a dose setting mechanism comprising a not self locking thread connection along which an injection button by rotation of a dose setting element relative to said housing is screwed out from the proximal end of the housing to project from this proximal end a distance determined by the angle of said rotation and which thread connection by axial returning of the injection button transforms this axial movement to a rotation of one of the piston drive elements relative to the other,

which syringe according to the invention is characterised in that

a unidirectional coupling is provided between the nut member and the piston rod guide allowing rotation of these parts relative to each other in one direction but not in the opposite direction, the allowed rotation being one by which the piston rod is transported in a distal di-

rection in the syringe, the coupling being so designed that a set initial reluctance has to be overcome before the rotation takes place.

During the setting of a dose a torque is exerted on the unidirectional coupling in the direction in which this coupling allows rotation after a set initial reluctance has been overcome. As this torque is a weak one resulting when the male and the female part of a not self locking thread connection is rotated relative to each other the initial reluctance can be made large enough to allow this rotation without causing any relative rotation of the parts in the coupling.

When the injection button is pressed the movement of this button is transformed into a rotation of the piston rod (or the nut member) relative to the nut member (or the piston rod). When the button is pressed hard enough the initial reluctans is overcome so that the two elements, the piston rod and the nut member, are rotated relative to each other.

According to the invention a click coupling providing an moderate resistance against rotation is established between the housing and the element rotated relative to the housing to set a dose. Hereby it is ensured that the position corresponding to a set dose is maintained and is not inadvertently altered. The clicks may be taken as an audible signal indicating the size of the set dose.

The unidirectional coupling may be a coupling comprising a pawl sliding over a pawl wheel with teeth having a steep front edge and a ramp shaped trailing edge, and the initial reluctance may be obtained by the fact that the trailing edges of the pawl wheel teeth has a depression engaged by a mating protrusion on the pawl.

A dose scale drum which has in its surface a helical track engaged by a helical rib on the inner side of the housing to form a not self locking thread connection between the housing and the drum may be coupled to the injection button to be moved axially with this button. This way the dose scale drum will be rotated relative to the housing when it is axially displaced with the injection button in said housing.

The thread connection by which the injection button is screwed out from the housing by setting a dose may be the thread connection between the dose scale drum and the housing. In this case the dose scale drum must be coupled to a driver rotating the piston rod (or the nut member) relative to the nut member (or the piston rod) when the injection button is pressed.

A dose is set by rotating an element relative to the housing, and this element may be an element carrying the nut member and the unidirectional coupling so that the rotation is transmitted through said unidirectional coupling to the dose setting drum. The rotation transmitted is in the direction in which the coupling can run free when an initial reluctance is overcome. However, the force needed to screw the dose scale drum up along its thread is not large enough to overcome said reluctance and consequently the rotation is transmitted through the coupling.

In one embodiment of the syringe according to the invention the element rotated relative to the housing may be a part carrying the nut member and the unidirectional coupling through which the rotation is transmitted to the dose setting drum.

In another embodiment of the syringe according to the invention the element rotated relative to the housing may be the injection button and the not self locking thread connection which determines the lifting of the injection button may be an inner thread in a bore in the injection butt on engaging an outer thread on an enlargement of the piston rod. When the injection button is screwed up along the piston rod to project from the housing a torque is exerted on the piston rod trying to rotate this piston rod in a direction which will move it in a distal direction in the syringe. Such a rotation is just the rotation which is allowed by the uniderectional coupling which blocks rotation in the opposite direction. Due to the initial reluctance against rotation of the coupling parts relative to each other the piston rod will not be rotated when the injection button is screwed up along it in a proximal direction in the syringe. If the injection button is screwed in the opposite direction the unidirectional coupling will definitively block a relative rotation of the piston rod and the nut member in the direction which would draw the piston rod in a proximal direction.

In the last mentioned embodiment of the injection syringe the dose scale drum may be mounted rotateable but not axially displaceable on the injection button. When the dose scale drum is moved with the injection button in the axial direction of the syringe the drum will be rotated due to the not self locking thread connection between said drum and the housing so that a number on the drum corresponding to the set dose is visible in a window provided in the wall of the housing. In this embodiment the pitch of the dose drum thread need not be identical with the pitch of the thread along which the injection button is screwed to set a

dose, only both thread connections must have a pitch large enough to make the thread connection the not self locking type, i.e. of the type by which an axial movement can be transformed into a rotation.

In an appropriate embodiment of the syringe according to the invention the dose scale drum is mounted rotatable but not axially displaceable on the injection button.

During the injection the injection button must be kept inrotatable but axially displaceable relative to the housing in the angular position to which the injection button is rotated during the setting of a dose. This may be obtained by letting the click coupling between the housing and the injection button comprise protrusions on one part engaging axial grooves in the other. When the injection button is pressed home into the housing the internal thread in the bore of this button will act on the engaging outer thread on the enlargement at the end of the piston rod and convert the axial movement of the injection button to a rotational movement of the piston rod in a direction by which the piston rod is screwed through the nut member in a distal direction in the syringe. The piston rod guide which is connected to one part of the unidirectional coupling is allowed to rotate when the initial reluctance against rotation in the direction else allowed by the coupling is overcome. Also a rotational movement of the dose scale drum is induced by the axial movement of the injection button so that the scale is returned to its zero position when the button is pressed home. When rotation of the dose scale drum and the piston rod is induced by the axial movement of the injection button this button is reacted upon by a torque which must be taken up by the click connection between the injection button and the housing which connection must consequently be strong enough to absorb this force without rotating.

In the following the invention is described in further details with references to the drawing, wherein

Figure 1 shows a front view of an embodiment of an injection syringe according to the invention,

Figure 2 shows a sectional view along the line II-II in figure 1,

Figure 3 shows in a reduced scale an exploded view of the syringe in figure 1,

Figure 4 shows a sectional view along the line IV-IV in figure 1,

Figure 5 shows a sectional view along the line V-V in figure 1,

Figure 6 shows a front view of another embodiment of an syringe according to the invention,

Figure 7 shows a sectional view along the line VII-VII in figure 6,

Figure 8 shows in a reduced scale an exploded view of the syringe in figure 6,

Figure 9 shows a sectional view along the line IX-IX in figure 6,

Figure 10 shows a sectional view along the line X-X in figure 6.

Figure 11 shows a sectional side view of another embodiment of a syringe according to the invention,

Figure 12 shows a sectional side view perpendicular to the view in figure 11,

Figure 13 shows in a reduced scale an exploded view of the syringe in figure 11 and 12,

Figure 14 shows a sectional side view of the dose setting part of another embodiment of a syringe according to the invention,

Figure 15 shows a sectional side view of still another embodiment of a syringe according to the invention,

Figure 16 shows a sectional side view perpendicular to the view in figure 15,

Figure 17 shows in a reduced scale an exploded view of the syringe in figure 15 and 16,

Initially it may be convenient to define that in this application directions of rotation are always seen from the proximal end of the pen and designed as clockwise or anticlockwise seen in this direction.

Figure 1 shows an injection syringe of the kind by which a liquid from an ampoule can be apportioned in a number of individually set does. Figure 3 shows an exploded view of this syringe and the figures 2, 4 and 5 sectional views taken along different lines in figure 1.

The syringe comprise a tubular housing 1 which is by a partition 15 divided into a first and a second division into the first one of which an ampoule holder 2 is snapped by a snap lock comprising a ring shaped bead 3 on the ampoule holder 2 which bead is snapped into a corresponding circumferantial grove in the inner wall of the housing 1 near an open end thereof. By this snap connection the ampoule holder 2 is secured in the housing 1 so that it can be rotated but not axially displaced relative to this housing.

In the syringe ready for use an ampoule is mounted in the ampoule holder which is then at its distal end closed by an end wall provided with a needle hub receiving part onto which a needle hub can be mounted having a needle with one end communicating with the content of the ampoule and the other end free to be inserted into a patient. In the shown syringe, however, neither ampoule, end wall nor needle hub are shown.

The end of the ampoule holder 2 inserted in the housing 1 is closed by a wall 4 having a central bore with an internal thread 5. A piston rod 6 having an external thread 7 mating the thread 5 of said bore extends through said bore. The threads are so designed that a clockwise rotation of the piston rod will drive this rod into an ampoule accommodating compartment 8 in the first division of the housing 1. At its end projecting into the compartment 8 the piston rod 6 is provided with a pressure foot 9 designed to abut a piston closing the rear end of an ampoule accommodated in the ampoule holder 2.

In the proximal side of the end wall 4 the bore is enlarged and the internal side of the enlargement is provided with pawl wheel teeth 10 having a steep front edge 11 facing the clockwise direction and a ramp shaped rear edge 12 facing the anticlockwise direction. At

least one pawl 13 mounted on a piston rod guide 14 co-operates with the pawl teeth 10 so that said piston rod guide can only be rotated clockwise in the ampoule holder 2.

On the inner wall of the second division of the housing 1 a helical protruding rib 16 is provided defining an inner thread with a high pitch. A dose scale drum 17 is in its outer wall provided with a helical grove defining a corresponding external thread mating the inner thread just mentioned. The pitch angle of the threads exceeds the angle of friction for the materials forming the parts of the thread connection and consequently the thread connection is of the not self locking type which induce a relative rotation of the parts of the connection when these part are moved axially relative to each other.

Numbers indicating set doses are printed on the outer wall of the dose drum 17 and the number corresponding to a set dose is shown in a window 18 provided in the side wall of the housing 1.

The dose scale drum 17 is provide with a tubular extension 21 having an end near the proximal end of the syringe. Said end of the extension is closed by an end wall 19 having a central outer protrusion 20. In a part of the wall adjacent to the end wall 19 the extension 21 is provided with slots 22. The said end of the extension is covered by a cup shaped cap 23 forming an injection button. Internal hooks 24 at the open end of this cap snaps over an external circumferential bead 25 on the extension 21 and the protrusion 20 on the end wall 19 abuts the inner side of the bottom of the cap 23 to form a journal about which the injection button can rotate relative to the extension 21 whereas it cannot be axially displaced relative to this extension.

A driver tube 26 integral with the piston rod guide 14 extends from this piston rod guide to the end wall 19 of the dose scale drum extension 21 and is at its proximal end divided into tongues 27 terminated by external hooks 28 engaging the slots 22 in the extension 21. This way the dose scale drum 17 is bound to rotate with the driver tube 26 but is axially displaceable relative to this tube.

To set a dose the ampoule holder 2 is rotated anticlockwise in the first division of the housing 1. This rotation is performed against a resistance presented due to the fact that a protrusion 30 on the outer wall of the ampoule holder rests in one of a number of depressions 31

circumferentially provided in the inner wall of said first division of the housing as shown in the cross-sectional view in figure 3. The angular spacing of the depressions are appropriately made so that a dose of one unit is set when the protrusion is moved from one depression to the neighbouring depression so that the number of clicks heard and felt during the dose setting rotation corresponds to the size of the set dose.

The rotation of the ampoule holder is due to the friction in the engaging threads 5 and 7 transmitted to the piston rod 6 and further through the unidirectional coupling to the piston rod guide 14 although the torque is transmitted in a such a direction that the pawl will intend to click over the pawl wheel teeth 10. However, before this click function is performed a reluctance have to be overcome. This reluctance is obtained by providing the pawl 13 with a protrusion 29 at its end engaging the pawl wheel teeth 10 and by providing depressions 32 in the ramp shaped edges 12 of the pawl wheel teeth into which depressions the protrusion 29 on the pawl 13 will rest. Before the clicking release of the coupling is obtained a torque sufficient to lift up the protrusion 29 of the pawl 13 from the depression 32 in the ramp shaped edge 12 must be provided. Altogether a moderate torque can be transmitted from the rotated ampoule holder 2 to the driver tube 26. As the hooks 28 at the proximal end of the driver tube 26 engage the slots 22 in the dose scale drum extension 21 the dose scale drum will be rotated and be screwed upwards in the second division of the housing 1 and the injection button 23 will be lifted to protrude from the proximal end of the housing 1. As only a small torque is needed to screw up the dose scale drum this is obtained without releasing the unidirectional coupling to its clicking release function mode. The size of the set dose can currently be seen on the part of the dose scale drum which is presented in the window 18. If a too large dose has been set the ampoule holder can be rotated in a clockwise direction until the number corresponding to the size of the wanted doe is presented in the window 18.

To inject the set dose the injection button 23 is pressed home into the housing 1. Thereby the dose scale drum 17 is pressed in the distal direction and due to the thread connection between said drum and the housing 1 a torque is exerted on the drum rotating this drum in a clockwise direction. Said torque is via the slots 22 in the drum extension 21 and the hooks 28 at the end of the driver tube 26 and this tube itself transmitted to the piston rod guide 14. The pawls 13 on the piston rod guide are allowed to rotate in the clockwise direction when the torque is strong enough to overcome the reluctance provided by the protrusions 29 on the pawls engaging the depressions 32 in the ramp shaped edges of the pawl wheel teeth.

Such a strong torque is provided if only the inject button 23 is pressed hard enough. The piston rod guide 14 will now rotate clockwise with the unidirectional coupling working in its clicking released mode and the piston rod will be rotated clockwise too and will thereby be screwed through the wall 4 further into the ampoule accommodating compartment 8. The unidirectional coupling will never allow an anticlockwise rotation of the piston rod guide and the piston and this way it is ensured that the pressure foot 9 will never be drawn out of abutment with the piston in a not shown ampoule in the compartment 8.

In the shown embodiment the end wall 4 with its threaded bore forms a nut member relative to which the piston rod is rotated by the piston rod guide 14 and the driver tube 26. Embodiments may be imagined wherein the piston rod guide is provided in the wall 4 and a nut element is rotated by the driver tube and such embodiment will not be beyond the scope of the invention.

Another embodiment is described with reference to the figures 6-10. Elements corresponding to elements in the embodiment described with references to the figures 1-5 are provided with the same reference numbers. Different from the embodiment in figure 1-5 is the fact that the injection button 23 and not the dose scale drum 17 is provided with an extension 33, and that the driver tube 26 is omitted. Further the injection button 23 is provided with a flange 32 which abuts the end of the housing when the injection button is pressed home. The extension 33 serves as a journal for the dose scale drum 17 which is free to rotate on this journal but bound to follow axial movements of the injection button 23 due to hooks 34 at the end of the extension 33. A longitudinal bore 35 in the injection button and its extension 33 is provided with an internal helical rib 36 engaging a corresponding helical groove in an enlargement 37 at the proximal end of the piston rod to form a thread connection between said button 23 and said piston rod 6. The pitch of this thread connection is so that a not self locking thread connection is formed.

To set a dose the injection button 23 is manually rotated in a clockwise direction Thereby this button is screwed outwards from the housing 1 as the piston rod 6 will through the piston rod guide 14 and the unidirectional coupling be kept inrotatable although said unidirectional coupling in influenced by a torque in its release direction, however, due to the provided initial reluctance the piston rod guide 14 will not immediately be rotatable. In its movement outwards the injection button 23 will draw the dose scale drum 17 with it. When this drum is

moved axially in the housing it will be rotated due to the not self locking thread connection between said drum 17 and the housing 1.

By this construction the thread along which the injection button is screwed outwards and the tread along which the dose scale drum is rotated in the housing may be different.

A click connection corresponding to the one established between the cartridge holder 2 and the housing 1 in the embodiment according to figure 1 is in the embodiment according to figure 6 appropriately provided between the injection button 23 and the housing 1 where one or more protrusions 38 provided on the inner wall of the housing engages grooves 39in a cylindrical outer wall of the button 23. Thereby axial movement of the injection button is allowed in all its possible angular positions.

When the injection button is pressed to inject a set dose said button will be maintained inrotatable during its axial movement as the locking between the above mentioned protrusions on the inner wall of the housing and grooves on the outer wall of the button is strong enough to absorb the torque exerted on the injection button when it drives the piston rod to rotation in a clockwise direction after having overcome the reluctance against rotation in the release direction of the unidirectional coupling.

The embodiment shown in figure 11, 12 and 13 has the housing 1 with the window 18. The end wall 4 with the internal thread 5 is provided in a separate member 40 which is mounted in an end of the housing, the member 40 having protrusions 41 engaging slots 42 in the housing to lock the member 40 to the housing 1. Further the member 40 has at its periphery longitudinal recesses 43 which are engaged by not shown internal ribs in the housing to lock the member 40 against rotation relative to the housing 1. Further protrusions 44 on the ampoule holder 2 engage the slots 42 to lock the ampoule holder 2 to the housing 1.

The piston rod 6 engages by its external thread 7 the internal thread of the end wall 4 and is at its end in the ampoule holder terminated by a pressure foot 9 relative to which the piston rod 6 is rotatable. A driver tube 45 is at one end provided with the pawl 13 which engages pawl wheel teeth in the member 40 and is held between a ring shaped wall 46 in the housing and the end wall 4 in the member 40 to keep the driver tube 45 from axial movement but allowing it to rotate. On its inner wall the driver tube 45 has a key engaging a longitudinal re-

cess in the piston rod 6. Thereby rotation of the driver tube is transmitted to the piston rod 6 whereas the piston rod can move freely in the axial direction of the driver tube 45. On its outer wall the driver tube 45 has an outer thread 47 which engages an inner thread 50 in a nut member 48 which has at its distal end a flange 49 and is at its proximal end provided with a part 51 with reduced diameter to which part one end of a tubular part 52 which at its other end carries a button 23 is secured.

In the proximal end of the housing 1 a bushing 53 is secured to be non rotatable an non displaceable relative to said housing 1 the rotational locking being obtained by lugs 54 at the proximal end of the housing engaging recesses 55 at the periphery of the bushing 53. A guide member 56 is longitudinally displaceable in the bushing 53 but inrotatable relative to said bushing and consequently relative to the housing 1. The guide member has at its distal end an annular end wall 57. The part 51 of the nut member 48 is passed through the opening of said end wall 57 and has a bead 58 gripping into a circuferential inner recess in the wall of annular opening through said end wall to keep the bushing 53 secured to said part 51 so that this part can be rotated but not axially displaced in relation to the bushing 53. The scale drum 17 is journalled on the nut member 48 and is held on this nut member by having a flange 90 held between the end wall 57 of the guide member 56 and the shoulder formed where the part 51 connects to the nut member 48.

The button 23 is held rotatably on the guide member 56 which has a ring bead 59 engaging a circumferential recess 60 in the inner wall of the button 23 which recess 60 is somewhat broader than than the bead 59 so that the button in excess of being rotatable on said bushing 53 can be axially displaced a distance defined by the width of the recess 60 relative to the width of the bead 59. The button 23 is coupled to the nut member 48 by internal ribs 61 in the tubular part 52 engaging slots 62 in the proximal part of the part 51 of the nut member 48. This coupling forces the button 23 and the nut member 48 to follow each other in rotational movements but allow a minor relative axial displacement.

The proximal end surface of the guide member 56 has one or more axially directed protrusions 63 which can co-operate with radial recesses 64 in the bottom of the button 23, but mainly a biasing keeps these recesses and protrusions out of engagement. Further the guide member has at its proximal end at least one radial protrusion 65 which is biased to engage axial recesses 66 in an inner wall of the button to produced a click sound each time the

button is rotated relative to the bushing so that the protrusion jump from one recess to the neighbour recess.

To set a dose the button 23 is rotated in a clockwise direction. This rotation is due to the coupling between the ribs 61 and the slots 62 transmitted to the nut member 48 which is then screwed in distal direction along the driver tube 45 which is held inrotatably in the housing due to the reluctans of the pawl 13 to move along the pawl teeth in the member 40. The movement of the nut member 48 in proximal direction makes the scale drum 17, the guide member 56, and the tubular part 52 with the button move in proximal direction so that the button is elevated over the end proximal end of the housing 1. A to high set dose can be reduced by rotating the button in an anti clockwise direction.

During the rotation of the button the radial protrusion 65 of the guide member 56 clicks from one axial recess 66 to the other. The distance between can appropriately be chosen so that a click corresponds to a changing of the set dose by one international unit up or down. Due to engagement between the helical grove on the cylinder wall of the scale drum and a helical rib on the inner wall of the housing the movement of the dose scale drum 17 will rotate and displace said drum so that the set dose is shown in the window 18.

When the dose scale drum is displaced outwardly in the housing a steep front side of a saw tooth 91 at the proximal end of the dose scale drum 18 will abut a steep front side of a similar tooth 92 on the bushing whereby the rotation of the dose scale drum is stopped to indicate that a maximum dose has been set.

To inject the set dose the button 23 is pressed. Thereby the bias keeping the protrusions 63 and the recesses 64 out of engagement is overcome and the said engagement is established. The button 23 is now locked relative to the guide element 56 which is again locked against rotation relative to the bushing 53 and consequently relative to the housing 1. The coupling between the tubular part 52 and the nut member 48 makes this nut member inrotatable relative to the housing so an axial movement of said nut member in a distal direction will due to the not self locking thread coupling between this nut element and the driver tube 45 make this driver tube 45 rotate in a clockwise direction and due to the key/groove coupling between the driver tube 45 and the piston rod 6 said piston rod will be screwed through the end wall 4 further into the ampoule holder compartment. The locking of the button 23

against rotation during the injection ensures that the set dose is not inadvertently changed during the injection.

In the embodiment shown in figure 14 separate buttons are provided for the dose setting and the injection. Corresponding to previously described embodiments this one has a housing 1 and a driver tube 67 which is rotatable in only one direction due to a pawl which engage pawl wheel teeth in a part secured in the distal end of the housing. Trapping of the pawl between the member 40 and a ring shaped wall 46 in the housing fixes the driver tube against axial movement. On the outer wall of the driver tube 67 an axial rib 68 is provided which rib engages an axial recess 69 in a tubular injection element 70 to transmit rotation of said injection element to the driver tube 67.

At the proximal end of the housing 1 a dose setting button 71 is mounted so that this button can be rotated but not axially displaced relative to the housing 1. This is obtained by the fact that the dose setting button 71 on a part fitting into the housing has a ring shaped bead 72 which engages a mating circuferential recess 73 in the inner wall of the housing. Outside the housing the dose setting button has a part having a diameter corresponding to or being larger than the diameter of said housing which part can be provided with axial ribs 74 to ensure a good grip by the setting of a dose. The dose setting button 71 has a central bore the inner wall of which has a helical recess 75 engaging a helical rib 76 provided on the outer wall of the proximal part of the injection element 70 which element passes through the bore of the dose setting button 71. The outer wall of the distal part of the injection element 70 forms a journal for the scale drum 17 which through an outer helical recess engaged by an internal helical rib 16 in the housing is rotated to show the set dose in the window 18 when the scale drum is displaced axially in the housing. The proximal end of the injection member is terminated by an end wall 77 which carries an injection button 78 which is by a pivot pin 79 journaled in a central bore in said end wall 77.

To set a dose the dose setting button 71 is rotated in a clockwise direction. As the injection member is kept non rotatable by its coupling to the driver tube 67 the collaboration between the helical recess 75 in the inner wall of the dose setting button 71 and the helical rib 76 on the outer wall of the injection element 70 will screw the injection element out through the dose setting button so that the injection button 78 is lifted up from the proximal end of the housing. Although the driver tube 67 with its pawl can be rotated in the clockwise direction

an initial torque is needed which is larger than the torque transmitted from the dose setting button to the injection element.

To inject a set dose the injection button 78 is pressed and the injection element is moved back into the housing. The co-operation of the helical recess 75 in the inner wall of the dose setting button 71 and the helical rib 76 on the outer wall of the injection element 70 will now make the injection element rotate in a clockwise direction and if only the injection button is pressed hard enough a torque is produced large enough to overcome the initial reluctance of the pawl mechanism against rotation in said clockwise direction.

The separation of the dose setting button 71 and the injection button 78 makes it less likely that the dose setting button is inadvertently operated during the injection.

Figure15, 16 and 17 illustrates still another embodiment. To maintain a clockwise rotation of a dose setting button for increasing the set dose the pawl mechanism working between the driver tube and the housing is turned so that it bars clockwise rotation and reluctantly allows anticlockwise rotation of the driver tube. Further the thread of the piston rod and the thread in the end wall of the housing is so designed that an anticlockwise rotation of the piston will screw the piston rod through said end wall and into the cartridge holder compartment. The piston rod has a not round cross-section and fits through the driver tube bore which has a corresponding not round cross-section. This way rotation is transmitted whereas the piston rod is allowed to move longitudinally through the driver tube.

A scale drum 80 is in its outer wall provided with a helical track which is engaged by a helical rib16 along the inner wall of the housing 1. At its proximal end the scale drum 80 has a diameter exceeding the inner diameter of the housing to form a dose setting button 81 which on its cylindrical outer wall is knurled to ensure a good finger grip.

A bushing 82 having a flange 83 at its proximal end and having a pair of opposite longitudinal slots 84 through its side walls fits into the scale drum 80 and over the driver tube 85 which tube has on its outer wall hooks 86 engaging the slots 84 of the bushing 82 whereby the bushing 82 and the driver tube 85 is coupled to each other so that rotation but not longitudinal displacement is transmitted between said two elements.

In the dose setting button a compartment is provided having a cylindrical side wall circumferentially provided with longitudinal recesses and a bottom with a rosette of teeth having a triangular cross-section. The flange 83 of the bushing 82 is adopted in said compartment and has at its periphery a radial protrusion 87 which is biased toward the side wall of the compartment. At its distal side the flange 83 has a rosette 93 of teeth which can be brought into engagement with the rosette at the bottom of the compartment.

The bushing 82 is mounted in the scale drum 80 with protrusion on the outer wall of the bushing 82 engaging recesses in the inner wall of the scale drum 80 so that a limited movement of the bushing in the scale drum is allowed so that the bushing can be moved axially relative to the scale drum to make or not make the teeth of said rosettes engage each other. An injection button 88 is rotatably mounted with a pivot pin 94 journaled in an end wall of the bushing 82.

When a dose is set by rotating the dose setting button 81 in a clockwise direction, the scale drum is screwed out of the housing and the dose setting button is lifted away from the proximal end of the housing. The bushing is kept non rotated due to its coupling to the driver tube which is locked against clockwise rotation and if a set dose is reduced by rotating the dose setting button 81 in an anticlockwise direction the pawl mechanism working between the driver tube and the housing is sufficient reluctant to rotate in its not blocking direction to prevent the bushing 82 from following this anticlockwise rotation. Therefore by the rotation of the dose setting button 81 in any direction the radial protrusion 87 on the flange 83 of the bushing 82 will click from one of the axial recess in the inner wall of the dose setting button 81 to the next one, the recesses being so spaced that one click corresponds to a chosen change of the set dose, e. g. one unit or a half unit. During the setting the rosette in the dose setting button forces the rosette 93 on the flange 83 of the bushing 82 out of engagement.

When the injection button 88 is pressed to inject the set dose the said rosettes are pressed into engagement so that the bushing 82 will follow the anticlockwise rotation of the dose setting button 81 which is induced by the thread engagement between the helical track of the scale drum 80 and the rib 16 in the housing when the scale drum 80 is pressed back into said housing. The bushing will rotate the driver tube 85 in an anticlockwise direction which

the pawl mechanism reluctantly allows an the piston rod is thereby screwed further into an ampoule 89 in the ampoule holder 2.

By this device the risk for inadvertent operation of the dose setting button 81 during the injection is eliminated. Further the device consist of a minimum of parts whereby the manufacturing is made easy.

CLAIMS

B An injection syringe

1. ~~An injection syringes~~ for apportioning set doses of a medicine from a cartridge containing an amount of medicine sufficient for the preparation of a number of therapeutic doses, comprising

B a housing ;

a piston rod having a not circular cross-section and an outer thread

a piston rod drive comprising two elements

a) a piston rod guide mating the not circular cross-section of the piston rod to allow axially displacement but not rotatation of the piston rod in relation to said piston rod guide, and

b) a nut member which is not axially displaceable in the housing and which has an inner thread mating the thread of the piston rod to form a self locking thread connection,

a dose setting mechanism comprising a not self locking thread connection along which an injection button by rotation of a dose setting element relative to said housing is screwed out from the proximal end of the housing to project from this proximal end a distance determined by the angle of said rotation and which thread connection by axial returning of the injection button transforms this axial movement to a rotation of one of the piston drive elements relative to the other, characterised in that a unidirectional coupling is provided between the nut member and the piston rod guide allowing rotation of these parts relative to each other in one direction but not in the opposite direction, the allowed rotation being one by which the piston rod is transported in a distal direction in the syringe, the coupling being so designed that an initial reluctance set large enough to resist a torque exerted on the coupling by the dose setting has to be overcome before rotation takes place.

2. An injection syringe according to claim 1, characterised in that a click coupling providing an moderate resistance against rotation in either directions is established between the housing and the element rotated relative to this housing to set a dose.

3. An injection syringe according to claim ~~1 or 2~~, characterised in that the unidirectional coupling comprises a pawl sliding over a pawl wheel with teeth having a steep front edge and a ramp shaped trailing edge.

4. An injection syringe according to claim 3, characterised in that the trailing edges of the pawl wheel teeth has a depression engaged by a mating protrusion on the pawl.

5. An injection syringe according to ~~anyone of the preceding claims~~ claim 1, characterised in that a dose scale drum has in its surface a helical track engaged by a helical rib on the inner side of the housing to form a not self locking thread connection between the housing, and that the dose scale drum and is coupled to the injection button to be moved axially with this button.

6. An injection syringe according to claim 5, characterised in that the thread connection by which the injection button is lifted by setting a dose is the thread connection between the dose scale drum and the housing.

7. An injection syringe according to claim 1, ~~2, 3, or 4~~ characterised in that the element rotated relative to the housing is the injection button and that the not self locking thread connection which determines the lifting of the injection button is an inner thread in a bore in the injection button engaging an outer thread on a part with enlarged diameter of the piston rod.

8. An injection syringe according to claim 1, ~~2, 3 or 4~~, characterised in that the piston rod guide is mounted in a driver tube in which tube the piston rod is axially displaceable but is rotated with said tube, and that the not self locking thread connection which determines the lifting of the injection button is provided between the driver tube and a part which is axially displaceable with the injection button.

COMBINED DECLARATION FOR PATENT APPLICATION AND POWER OF ATTORNEY
(Includes Reference to PCT International Applications)

Attorney's Docket Number: 2.200-US

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

An Injection Syringe

the specification of which (check only one item below):

[ ] is attached hereto

[X] was filed as United States application

Application No. to be assigned

on January 28, 1999

and was amended

on _____

[ ] was filed as PCT international application

Number _____

on _____

and was amended under PCT Article 19

on _____

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability of this application in accordance with Title 37, Code of Federal Regulations, §1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign applications(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign applications(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed:

PRIOR FOREIGN/PCT APPLICATION(S) AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. 119:

COUNTRY (if PCT, indicate "PCT")	APPLICATION NUMBER	DATE OF FILING (day, month, year)	PRIORITY CLAIMED UNDER 35 USC 119
DK	PA 1998 00130	30 January 1998	[x] YES [ ] NO
US	60/073,820	5 February 1998	[x] YES [ ] NO
			[ ] YES [ ] NO
			[ ] YES [ ] NO
			[ ] YES [ ] NO
			[ ] YES [ ] NO

COMBINED DECLARATION FOR PATENT APPLICATION AND POWER OF ATTORNEY
(Includes Reference to PCT International Applications)

Attorney's Docket Number: 1.200-US

I hereby claim the benefit under Title 35, United States Code §120 of any United States application(s) or PCT international application(s) designating the United States of America that is/are listed below and, insofar as the subject matter of each of the claims of this applications is not disclosed in that/those prior application(s) in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application(s) and the national or PCT international filing date of this application:

PRIOR U.S. APPLICATIONS OR PCT INTERNATIONAL APPLICATIONS DESIGNATING THE U.S. FOR BENEFIT UNDER 35 U.S.C. 120:

U.S. APPLICATIONS		STATUS (Check one)		
U.S. APPLICATION NUMBER	U.S. FILING DATE	Patented	Pending	Abandoned

PCT APPLICATIONS DESIGNATING THE U.S.					
APPLICATION NO.	FILING DATE	US SERIAL NUMBER ASSIGNED (if any)			

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.
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3	Full Name of Inventor	Family Name	First Given Name	Second Given Name
	Residence & Citizenship	City	State or Foreign Country	Country of Citizenship
	Post Office Address	Post Office Address	City	State & Zip Code/Country

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Signature of Inventor 1	Signature of Inventor 2	Signature of Inventor 3
Date	Date	Date

PTO 1391 (REV. 10-83)

PRINT OF DRAWINGS
AS ORIGINALLY FILED

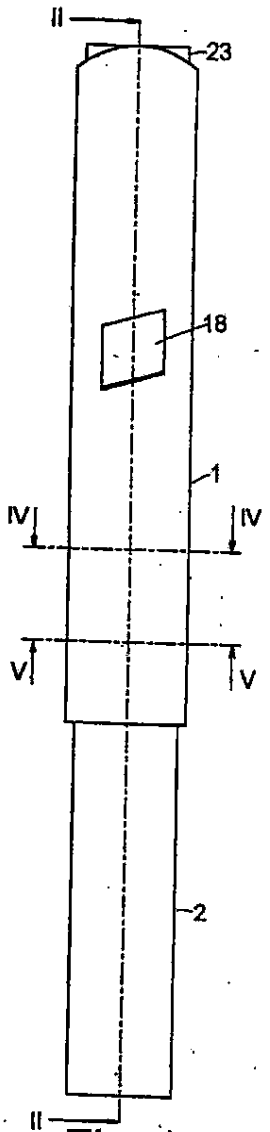

Fig. 1

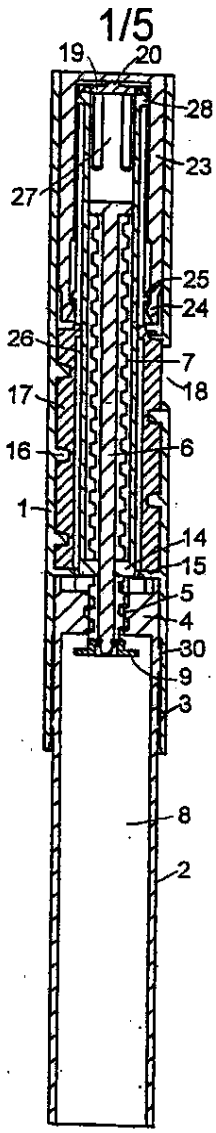

Fig.2

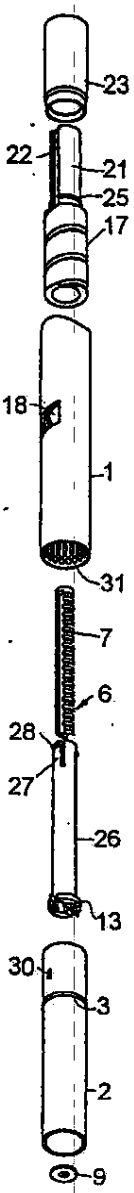

Fig.3

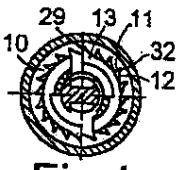

Fig.4

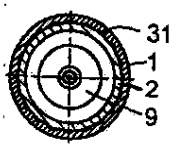

Fig. 5

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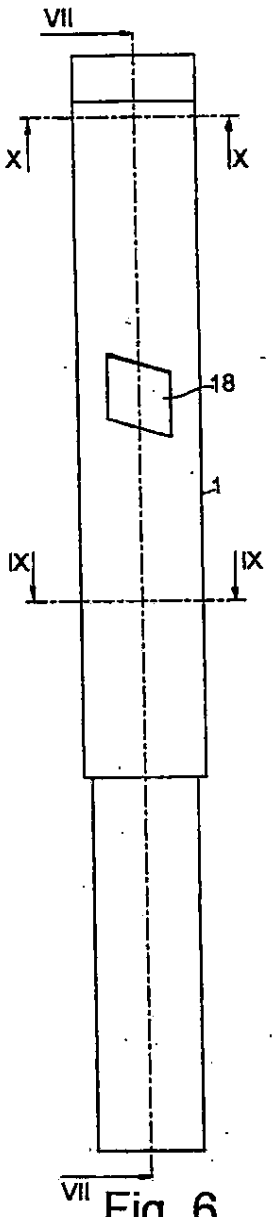

Fig. 6

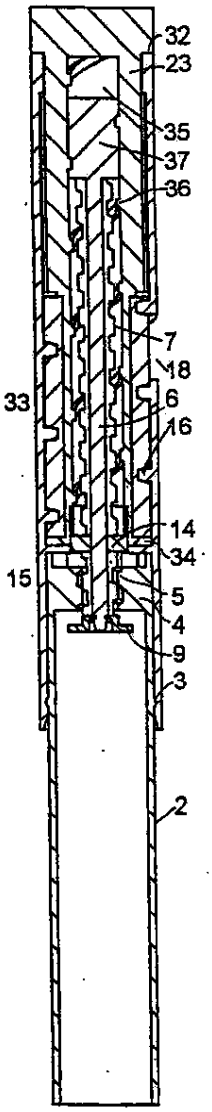

Fig. 7

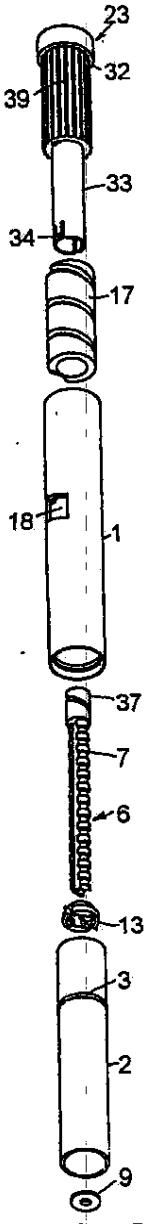

Fig.8

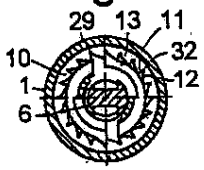

Fig. 9

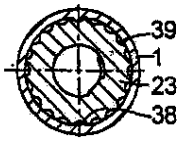

Fig.10

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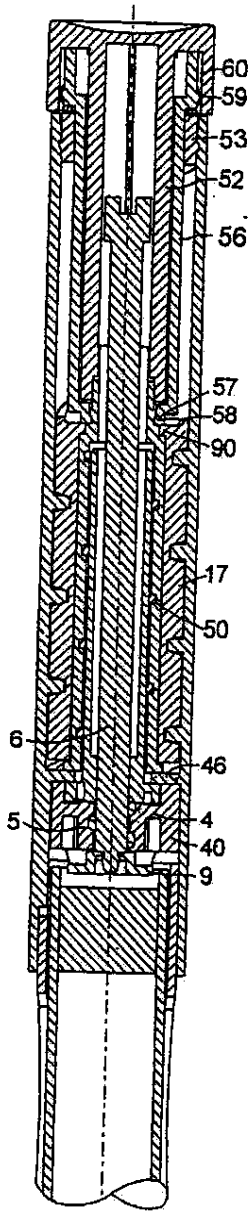

Fig. 11

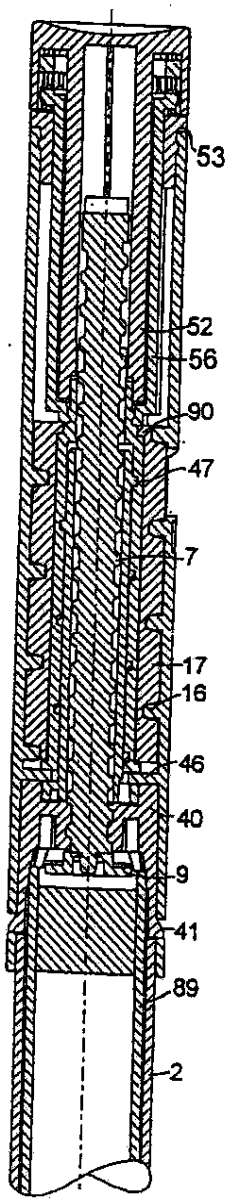

Fig. 12

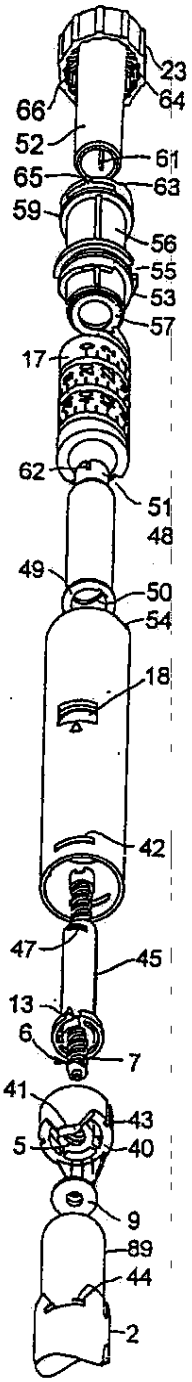

Fig. 13

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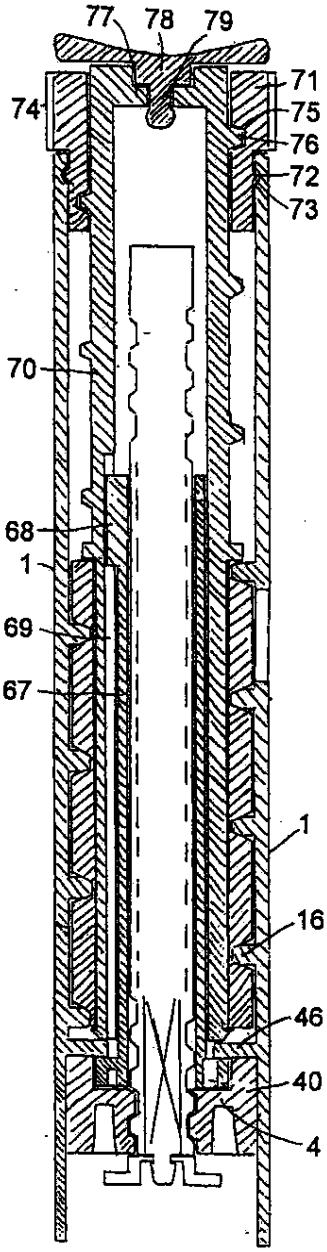

Fig. 14

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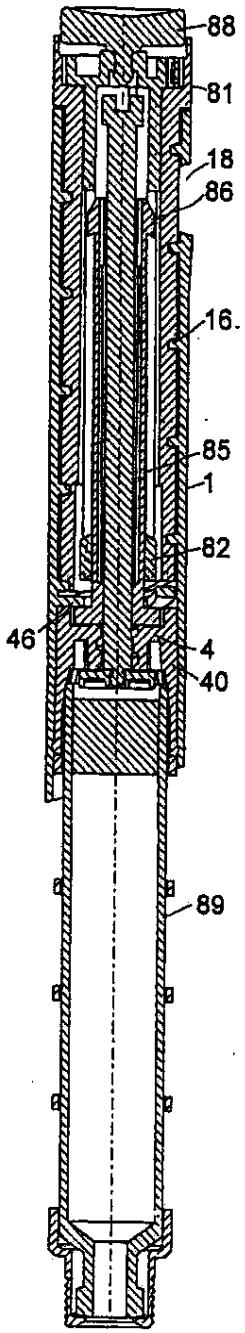

Fig. 15

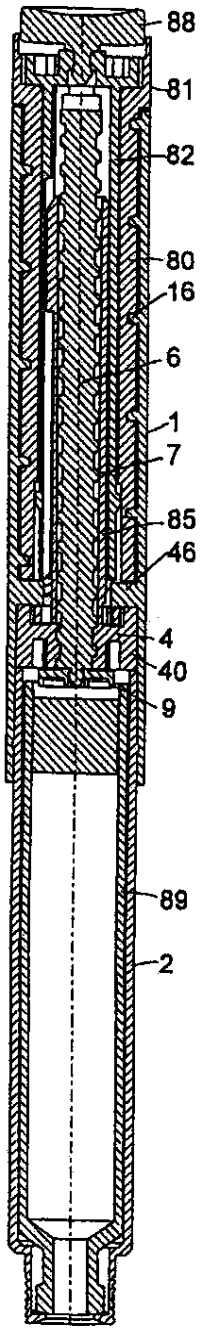

Fig.16

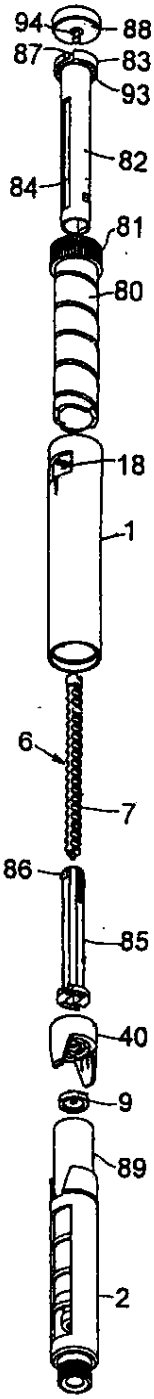

Fig. 17

APPROVED BY DRAFTSMAN	O.G. FIG. 2	
	CLASS 604	SUBCLASS 207

6004297

1/5

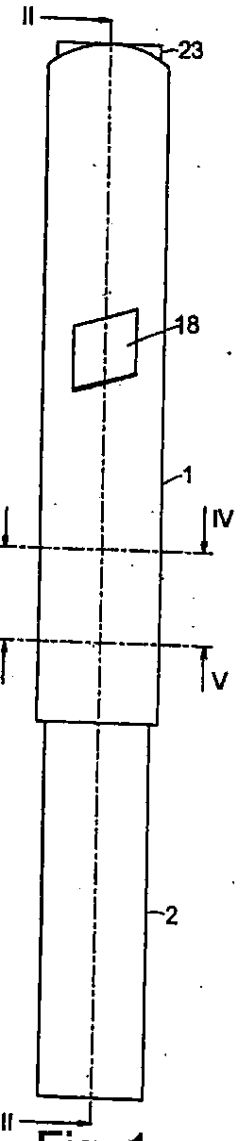

Fig. 1

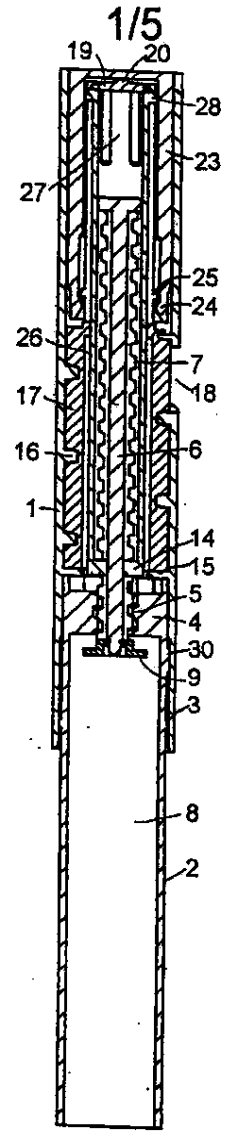

Fig.2

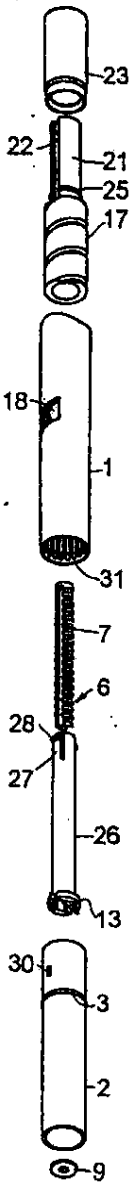

Fig.3

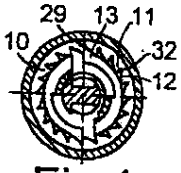

Fig.4

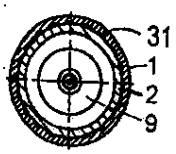

Fig. 5

APPROVED BY DRAFTSMAN	O.G. FIG.	
	CLASS	SUBCLASS

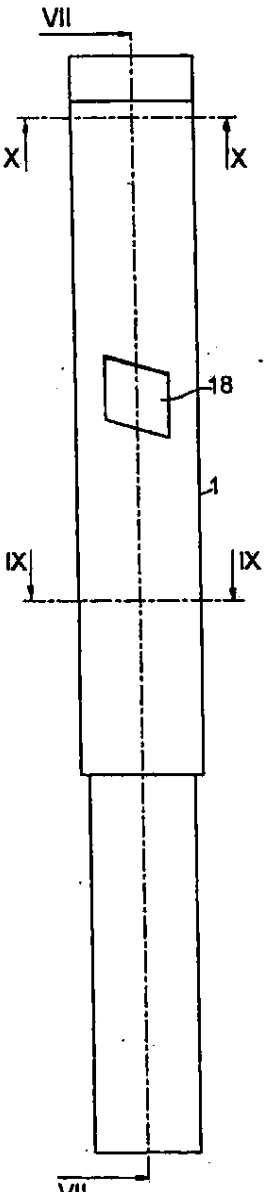

Fig. 6

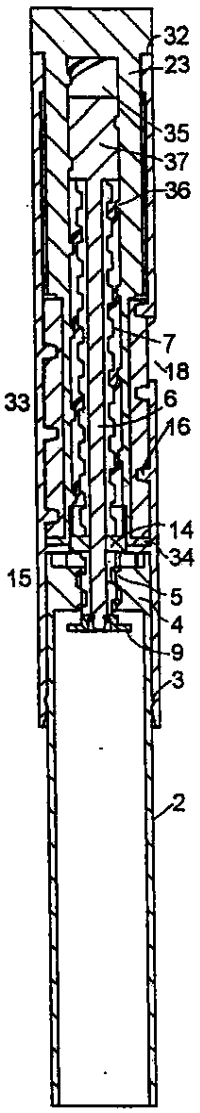

Fig. 7

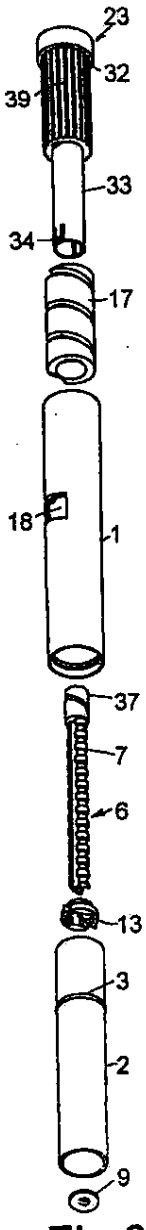

Fig.8

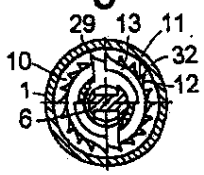

Fig. 9

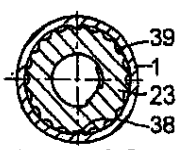

Fig.10

APPROVED BY DRAFTSMAN	O.G. FIG.	
	CLASS	SUBCLASS

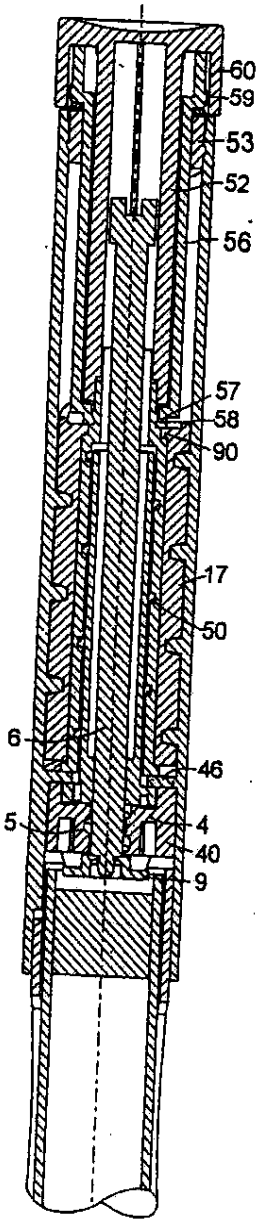

Fig. 11

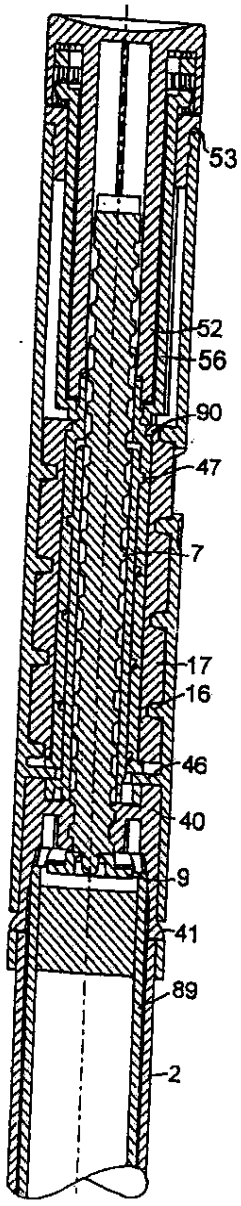

Fig. 12

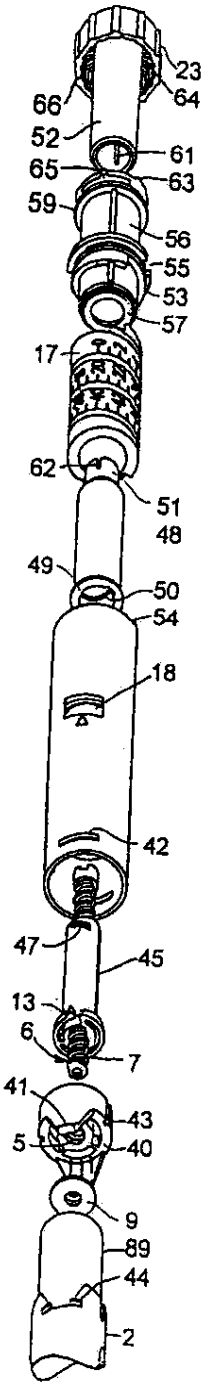

Fig. 13

APPROVED BY DRAFTSMAN	O.G. FIG.	
	CLASS	SUBCLASS

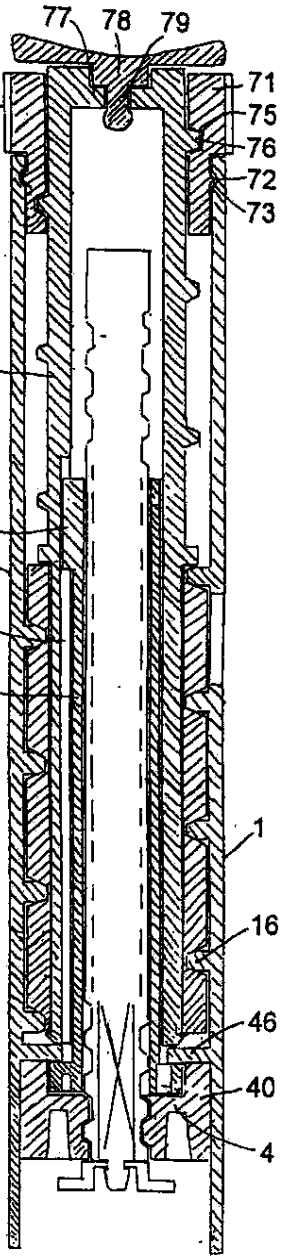

Fig. 14

APPROVED BY DRAFTSMAN	O.G. FIG.	
	CLASS	SUBCLASS

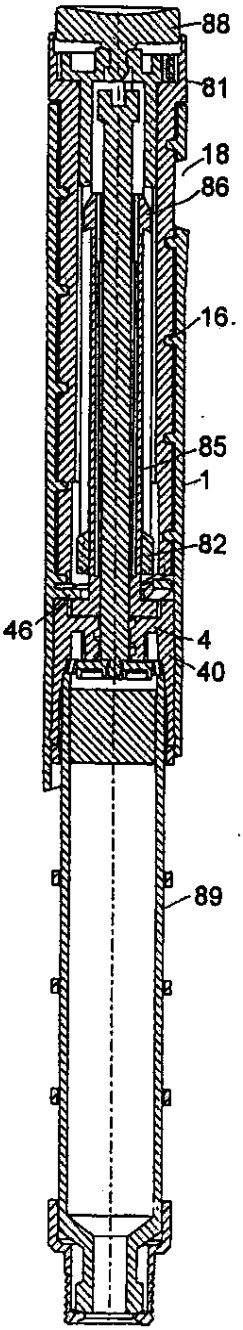

Fig. 15

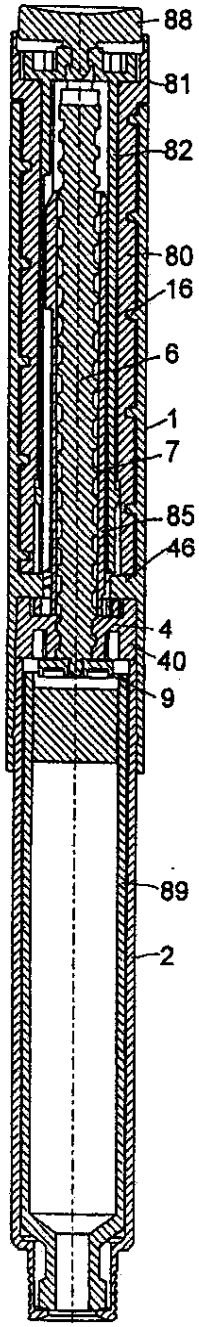

Fig.16

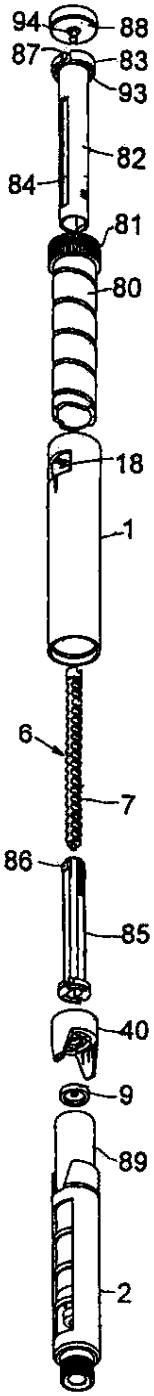

Fig. 17

PATENT APPLICATION FEE DETERMINATION RECORD

Effective November 10, 1998

Application or Docket Number: 09/238849

CLAIMS AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA
BASIC FEE		
TOTAL CLAIMS	8 minus 20=	*
INDEPENDENT CLAIMS	1 minus 3 =	*
MULTIPLE DEPENDENT CLAIM PRESENT		

* If the difference in column 1 is less than zero, enter "0" in column 2

SMALL ENTITY TYPE ☐		OR	OTHER THAN SMALL ENTITY	
RATE	FEE		RATE	FEE
	380.00	OR		760.00
X$ 9=		OR	X$18=	
X39=		OR	X78=	
+130=		OR	+260=	
TOTAL		OR	TOTAL	760

CLAIMS AS AMENDED - PART II

AMENDMENT A	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	*	Minus	**	=
Independent	*	Minus	***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				

SMALL ENTITY		OR	OTHER THAN SMALL ENTITY	
RATE	ADDITIONAL FEE		RATE	ADDITIONAL FEE
X$ 9=		OR	X$18=	
X39=		OR	X78=	
+130=		OR	+260=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

AMENDMENT B	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	*	Minus	**	=
Independent	*	Minus	***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				

RATE	ADDITIONAL FEE		RATE	ADDITIONAL FEE
X$ 9=		OR	X$18=	
X39=		OR	X78=	
+130=		OR	+260=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

AMENDMENT C	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	*	Minus	**	=
Independent	*	Minus	***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				

RATE	ADDITIONAL FEE		RATE	ADDITIONAL FEE
X$ 9=		OR	X$18=	
X39=		OR	X78=	
+130=		OR	+260=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20."
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3."
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

FORM PTO-875
(Rev 6/98)

Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

MULTIPLE DEPENDENT CLAIM FEE CALCULATION SHEET

(FOR USE WITH FORM PTO-875)

SERIAL NO.	FILING DATE
APPLICANT(S)	

CLAIMS

	AS FILED		AFTER 1st AMENDMENT		AFTER 2nd AMENDMENT	
	IND.	DEP.	IND.	DEP.	IND.	DEP.
1	1					
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TOTAL IND.						
TOTAL DEP.						
TOTAL CLAIMS	3					

	*		*		*	
	IND.	DEP.	IND.	DEP.	IND.	DEP.
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98						
99						
100						
TOTAL IND.						
TOTAL DEP.						
TOTAL CLAIMS						

* MAY BE USED FOR ADDITIONAL CLAIMS OR AMENDMENTS

FORM PTO-1360 (REV. 3-78)

U.S.DEPARTMENT OF COMMERCE
Patent and Trademark Office

SERIAL NUMBER	FILING DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
09/238,849	01/28/99	604	3734	5472.200-US

APPLICANT

SOREN STEENFELDT-JENSEN, HORNBAEK, DENMARK; STEFFEN HANSEN, HILLEROD, DENMARK.

6.M.c.00

CONTINUING DOMESTIC DATA********
VERIFIED PROVISIONAL APPLICATION NO. 60/073,820 02/05/98

371 (NAT'L STAGE) DATA********
VERIFIED None

FOREIGN APPLICATIONS********
VERIFIED DENMARK 00130/98 01/30/98

Foreign Priority claimed 35 USC 119 (a-d) conditions met / Verified and Acknowledged	STATE OR COUNTRY	SHEETS DRAWING	TOTAL CLAIMS	INDEPENDENT CLAIMS
☒yes ☐no ☒yes ☐no ☐Met after Allowance — Examiner's Initials / Initials	DKX	5	8	1

ADDRESS

STEVE T ZELSON
NOVO NORDISK OF NORTH AMER INC
405 LEXINGTON AVE
SUITE 6400
NEW YORK NY 10174-6401

TITLE

INJECTION SYRINGE

FILING FEE RECEIVED	FEES: Authority has been given in Paper No. _____ to charge/credit DEPOSIT ACCOUNT NO. _____ for the following:	☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit
$760		

A

Attorney Docket No.: 5472.200-US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
FILING UNDER 37 C.F.R. 1.53(b)

Box Patent Application
Assistant Commissioner for Patents
Washington, DC 20231

Express Mail Label No. EL021370315US
Date of Deposit January 28, 1999

Sir:

This is a request for filing an application under 37 C.F.R. 1.53(b) of

Applicant(s): Steenfeldt-Jensen et al.

Title: An Injection Syringe

21 pages of specification 5 sheets of formal drawings

2 sheets of Declaration and Power of Attorney

[x] The filing fee is calculated as follows:

Basic Fee:	$760.00
Total Claims: 8 - 20 = 0 x 18 =	$0
Independent Claims: 1 - 3 = 0 x 78 =	$0
Total Fee:	$760.00

Priority of Danish application serial no. PA 1998 00130/98 filed on January 30, 1998 is claimed under 35 U.S.C. 119. A certified copy thereof is submitted herewith.

Priority of U.S. provisional application serial no. 60/073,820 filed on February 5, 1998 is claimed under 35 U.S.C. 119.

Address all future communications to Steve T. Zelson, Esq., Novo Nordisk of North America, Inc., 405 Lexington Avenue, Suite 6400, New York, NY 10174-6401.

Please charge the required fee, estimated to be $760, to Novo Nordisk of North America, Inc., Deposit Account No. 14-1447. A duplicate of this sheet is enclosed.

Respectfully submitted,

Date: January 28, 1999

Elias J. Lambiris, Reg. No. 33,728
Novo Nordisk of North America, Inc.
405 Lexington Avenue, Suite 6400
New York, NY 10174-6401
(212) 867-0123

Attorney Docket No.: 5472.200-US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

EXPRESS MAIL CERTIFICATE

Box Patent Application
Assistant Commissioner for Patents
Washington, DC 20231

Re: U.S. Patent Application for
"An Injection Syringe"
Applicants: Steenfeldt-Jensen et al.

Sir:

Express Mail Label No. EL021370315US

Date of Deposit January 28, 1999

I hereby certify that the following attached paper(s) or fee

1. Filing Under 37 C.F.R. 1.53(b) (in duplicate)
2. Patent Application
3. Unexecuted Combined Declaration and Power of Attorney
4. Preliminary Amendment
5. Certified Copy of Priority Application
6. 5 Sheets of Drawings

are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" under 37 C.F.R. 1.10 on the date indicated above and is addressed to the Commissioner of Patents and Trademarks, Washington, DC 20231.

Gina Maldonado
(Name of person mailing paper(s) or fee)

(Signature of person mailing paper(s) or fee)

Mailing Address:

Novo Nordisk of North America, Inc.
405 Lexington Avenue, Suite 6400
New York, NY 10017
(212) 867-0123

Attorney Docket No.: 5472.200-US PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Steenfeldt-Jensen et al.

Serial No.: To be assigned Group Art Unit: To be assigned

Filed: January 28, 1999 Examiner: To be assigned

For: An Injection Syringe

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

Before the above-captioned application is taken up for examination, entry of the following amendment is respectfully requested:

IN THE SPECIFICATION:

At page 1, before the first line, insert

--CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims priority under 35 U.S.C. 119 of Danish application PA 1998 00130 filed January 30, 1998 and of U.S. provisional no. 60/073,820 filed February 5, 1998, the contents of which are fully incorporated herein by reference.--

IN THE CLAIMS:

Please amend claim 3 as follows:

At line 1, delete "or 2".

Please amend claim 5 as follows:

At line 1, delete "anyone of the preceding claims" and insert --claim 1--.

Please amend claim 7 as follows:

At ~~line 1~~, delete "2, 3, or 4,".

Please amend claim 8 as follows:

At line 1, delete "2, 3 or 4,".

REMARKS

This amendment is submitted to correct improper multiple dependent claims. Since only dependencies are altered, there is no new matter added, and entry of the amendment is respectfully requested.

Respectfully submitted,

Date: January 28, 1999

Elias J. Lambiris, Reg. No. 33,728
Novo Nordisk of North America, Inc.
405 Lexington Avenue, Suite 6400
New York, NY 10174-6401
(212) 867-0123

Kongeriget Danmark

Patent application No.: 0130/98

Date of filing: 30 Jan 1998

Applicant: Novo Nordisk A/S, Novo Allé, DK-2880 Bagsværd, DK

This is to certify the correctness of the following information:

The attached photocopy is a true copy of the following document:

- The specification, claims and drawings as filed with the application on the filing date indicated above.

Patentdirektoratet · Kongeriget Danmark ·

Erhvervsministeriet
Patentdirektoratet

TAASTRUP 13 Jan 1999

Jytte Hansen
Kontorfuldmægtig

0130 9830 JAN.88

An injection syringe

The invention relates to injection syringes of the kind apportioning set doses of a medicine from a cartridge containing an amount of medicine sufficient for the preparation of a number of therapeutic doses.

Such syringes are mainly made for users who have to inject themselves frequently, e. g. diabetics. A number of demands are set to such syringes. The setting of a dose must be easy an unambiguous and it must be easy to read the set dose. It must be possible with a minimum of trouble to cancel or change a wrongly set dose and when the dose is injected the dose setting must return to zero . When a disposable syringe is in question, i.e. a syringe which is disposed of when the cartridge is empty, the syringe must further be cheap and made of materials suited for recycling or burning without producing noxious gases. For these purposes the number of parts from which the syringe is constructed and the number of different kinds of materials used in the syringe should be kept at a minimum.

Most dose setting devices work with a threaded piston rod co-operating with a nut where the nut and the piston rod may be rotated relative to each other. The dose setting may be obtained by screwing the nut away from a stop to which it is returned during the injection by pressing the piston rod until the nut member abuts the stop. By other dose setting devices one of the elements, the nut or the piston rod, is kept inrotatable and the other is allowed to rotate a set angle depending on the set dose, whereby the piston rod is screwed a distance through the nut.

In most syringes for apportioning set doses it is preferred that the piston rod is backing up the piston upon which it works during the injection. To obtain this precaution is taken to prevent the piston rod from moving in a proximal direction.

The syringe according to EP 327 910 is of the type wherein a nut is screwed away from a stop. During the setting of the dose the screwing may be performed in both direction so that a too large set dose may be lowered just by rotating the nut in an opposite direction. Means are provided preventing that negative doses are set. The mutual rotation of the piston rod and the nut is obtained by rotating a cap relative to the pen housing and a set dose may be

read on a scale and a pointer provided at adjacent edges of the housing and the cap, these edges being so shaped that the cap can only be mounted firmly on the housing when the pointer points zero on the scale. It may be seen as a weak point that doses larger than the one obtained by rotating the parts 360° must be calculated by adding the number pointed at on the scale and a number printed on the side of a tubular extension of the nut which is moved out from the proximal end of the housing proportionally with the dose set and which tubular extension is closed at its proximal end to form an injection button.

In EP 450 905 the above drawback is overcome by writing the numbers along a helical line on a tubular extension of the nut so that these number may successively be seen in a window in a housing element enclosing said tubular extension. Hereby the size of the dose is indicated unambiguously but the user have to remember to set the dose setting device on zero before the next setting of a dose is performed. If this is forgotten a wrong dose may be set and the number may not be seen clearly in the window.

In EP 608 343 is described a pen having a dose setting mechanism wherein the dose is set by rotating a button relative to a housing to set a dose. By the rotation the button is screwed up from the end of the housing in a thread having a pitch so large that the thread connection is not self blocking, i. e. when the button is presses back to the end of the housing it will rotate back in the thread. The button is through a ratchet coupled to a driver, the ratchet forming a unidirectional coupling which during the rotation of the button in one direction to set a dose rides or clicks over the teeth of the ratchet. The cylindrical side of the button carries numbers which shows the size of the set dose in a window when the button is screwed outward. When the button is screwed back the unidirectional coupling will transmit the rotation to the driver which has a nut co-operating with a threaded piston rod which is made inrotatable in a housing . This thread connection has a pitch which makes the nut self locking on the piston rod. A set dose may be cancelled by drawing the engaging parts of the ratchet out of engagement against the force of a spring so that the rotation of the button is not transmitted to the driver and then press the button back to the housing . This pen fulfils all the objects mentioned only the dose cancelling procedure is a little troublesome as the dose set button cannot as it will come most naturally just be screwed back if a too large dose is set. Concomitantly forcing the coupling parts apart against the force of the spring and pressing or

screwing the button back may be a little difficult and the demand for a spring necessitates use of metal parts in the syringe.

It is an object of the invention to provide a syringe which has the mentioned advantageous features without having the drawbacks known from existing syringes.

This is obtained by an injection syringes for apportioning set doses of a medicine from a cartridge containing an amount of medicine sufficient for the preparation of a number of therapeutic doses, comprising

a housing

a piston rod having a not circular cross-section and an outer thread

a piston rod drive comprising two elements

a) a piston rod guide in relation to which the piston rod is axially displaceable but not rotatable, and

b) a nut member which is rotatable but not axially displaceable in the housing and which has an inner thread mating the thread of the piston rod to form a self locking thread connection,

a dose setting mechanism comprising a not self locking thread connection along which an injection button by rotation of a dose setting element relative to said housing is screwed out from the proximal end of the housing to project from this proximal end a distance determined by the angle of said rotation and which thread connection by axial returning of the injection button transforms this axial movement to a rotation of one of the piston drive elements relative to the other,

which syringe according to the invention ischaracterised in that

a unidirectional coupling is provided between the nut member and the piston rod guide allowing rotation of these parts relative to each other in one direction but not in the opposite direction, the allowed rotation being one by which the piston rod is transported in a distal direction in the syringe, the coupling being so designed that a set initial reluctance has to be overcome before the rotation takes place.

During the setting of a dose a torque is exerted on the unidirectional coupling in the direction in which this coupling allows rotation after a set initial reluctance has been overcome. As this torque is a weak one resulting when the male and the female part of a not self locking thread connection is rotated relative to each other the initial reluctance can be made large enough to allow this rotation without causing any relative rotation of the parts in the coupling.

When the injection button is pressed the movement of this button is transformed into a rotation of the piston rod (or the nut member) relative to the nut member (or the piston rod). When the button is pressed hard enough the initial reluctans is overcome so that the two elements, the piston rod and the nut member, are rotated relative to each other.

According to the invention a click coupling providing an moderate resistance against rotation is established between the housing and the element rotated relative to the housing to set a dose. Hereby it is ensured that the position corresponding to a set dose is maintained and is not inadvertently altered. The clicks may be taken as an audible signal indicating the size of the set dose.

The unidirectional coupling may be a coupling comprising a pawl sliding over a pawl wheel with teeth having a steep front edge and a ramp shaped trailing edge, and the initial reluctance may be obtained by the fact that the trailing edges of the pawl wheel teeth has a depression engaged by a mating protrusion on the pawl.

A dose scale drum which has in its surface a helical track engaged by a helical rib on the inner side of the housing to form a not self locking thread connection between the housing and the drum may be coupled to the injection button to be moved axially with this button. This way the dose scale drum will be rotated relative to the housing when it is axially displaced with the injection button in said housing.

The thread connection by which the injection button is screwed out from the housing by setting a dose may be the thread connection between the dose scale drum and the housing. In this case the dose scale drum must be coupled to a driver rotating the piston rod (or the nut member) relative to the nut member (or the piston rod) when the injection button is pressed.

A dose is set by rotating an element relative to the housing, and this element may be an element carrying the nut member and the unidirectional coupling so that the rotation is transmitted through said unidirectional coupling to the dose setting drum. The rotation transmitted is in the direction in which the coupling can run free when an initial reluctance is overcome. However, the force needed to screw the dose scale drum up along its thread is not large enough to overcome said reluctance and consequently the rotation is transmitted through the coupling.

In one embodiment of the syringe according to the invention the element rotated relative to the housing may be a part carrying the nut member and the unidirectional coupling through which the rotation is transmitted to the dose setting drum.

In another embodiment of the syringe according to the invention the element rotated relative to the housing may be the injection button and the not self locking thread connection which determines the lifting of the injection button may be an inner thread in a bore in the injection butt on engaging an outer thread on an enlargement of the piston rod. When the injection button is screwed up along the piston rod to project from the housing a torque is exerted on the piston rod trying to rotate this piston rod in a direction which will move it in a distal direction in the syringe. Such a rotation is just the rotation which is allowed by the uniderectional coupling which blocks rotation in the opposite direction. Due to the initial reluctance against rotation of the coupling parts relative to each other the piston rod will not be rotated when the injection button is screwed up along it in a proximal direction in the syringe. If the injection button is screwed in the opposite direction the unidirectional coupling will definitively block a relative rotation of the piston rod and the nut member in the direction which would draw the piston rod in a proximal direction.

In the last mentioned embodiment of the injection syringe the dose scale drum may be mounted rotateable but not axially displaceable on the injection button. When the dose scale

drum is moved with the injection button in the axial direction of the syringe the drum will be rotated due to the not self locking thread connection between said drum and the housing so that a number on the drum corresponding to the set dose is visible in a window provided in the wall of the housing. In this embodiment the pitch of the dose drum thread need not be identical with the pitch of the thread along which the injection button is screwed to set a dose, only both thread connections must have a pitch large enough to make the thread connection the not self locking type, i.e. of the type by which an axial movement can be transformed into a rotation.

In an appropriate embodiment of the syringe according to the invention the dose scale drum is mounted rotatable but not axially displaceable on the injection button.

During the injection the injection button must be kept inrotatable but axially displaceable relative to the housing in the angular position to which the injection button is rotated during the setting of a dose. This may be obtained by letting the click coupling between the housing and the injection button comprise protrusions on one part engaging axial grooves in the other. When the injection button is pressed home into the housing the internal thread in the bore of this button will act on the engaging outer thread on the enlargement at the end of the piston rod and convert the axial movement of the injection button to a rotational movement of the piston rod in a direction by which the piston rod is screwed through the nut member in a distal direction in the syringe. The piston rod guide which is connected to one part of the unidirectional coupling is allowed to rotate when the initial reluctance against rotation in the direction else allowed by the coupling is overcome. Also a rotational movement of the dose scale drum is induced by the axial movement of the injection button so that the scale is returned to its zero position when the button is pressed home. When rotation of the dose scale drum and the piston rod is induced by the axial movement of the injection button this button is reacted upon by a torque which must be taken up by the click connection between the injection button and the housing which connection must consequently be strong enough to absorb this force without rotating.

In the following the invention is described in further details with references to the drawing, wherein

Figure 1 shows a front view of an embodiment of an injection syringe according to the invention,

Figure 2 shows a sectional view along the line II-II in figure 1,

Figure 3 shows in a reduced scale an exploded view of the syringe in figure 1,

Figure 4 shows a sectional view along the line IV-IV in figure 1,

Figure 5 shows a sectional view along the line V-V in figure 1,

Figure 6 shows a front view of another embodiment of an syringe according to the invention,

Figure 7 shows a sectional view along the line VII-VII in figure 6,

Figure 8 shows i a reduced scale an exploded view of the syringe in figure 6,

Figure 9 shows a sectional view along the line IX-IX in figure 6, and

Figure 10 shows a sectional view along the line X-X in figure 6.

Initially it may be convenient to define that in this application directions of rotation are always seen from the proximal end of the pen and designed as clockwise or anticlockwise seen in this direction.

Figure 1 shows an injection syringe of the kind by which a liquid from an ampoule can be apportioned in a number of individually set does. Figure 3 shows an exploded view of this syringe and the figures 2, 4 and 5 sectional views taken along different lines in figure 1.

The syringe comprise a tubular housing 1 which is by a partition 15 divided into a first and a second division into the first one of which an ampoule holder 2 is snapped by a snap lock comprising a ring shaped bead 3 on the ampoule holder 2 which bead is snapped into a cor-

responding circumferantial grove in the inner wall of the housing 1 near an open end thereof. By this snap connection the ampoule holder 2 is secured in the housing 1 so that it can be rotated but not axially displaced relative to this housing.

In the syringe ready for use an ampoule is mounted in the ampoule holder which is then at its distal end closed by an end wall provided with a needle hub receiving part onto which a needle hub can be mounted having a needle with one end communicating with the content of the ampoule and the other end free to be inserted into a patient. In the shown syringe, however, neither ampoule, end wall nor needle hub are shown.

The end of the ampoule holder 2 inserted in the housing 1 is closed by a wall 4 having a central bore with an internal thread 5. A piston rod 6 having an external thread 7 mating the thread 5 of said bore extends through said bore. The threads are so designed that a clockwise rotation of the piston rod will drive this rod into an ampoule accommodating compartment 8 in the first division of the housing 1. At its end projecting into the compartment 8 the piston rod 6 is provided with a pressure foot 9 designed to abut a piston closing the rear end of an ampoule accommodated in the ampoule holder 2.

In the proximal side of the end wall 4 the bore is enlarged and the internal side of the enlargement is provided with pawl wheel teeth 10 having a steep front edge 11 facing the clockwise direction and a ramp shaped rear edge 12 facing the anticlockwise direction. At least one pawl 13 mounted on a piston rod guide 14 co-operates with the pawl teeth 10 so that said piston rod guide can only be rotated clockwise in the ampoule holder 2.

On the inner wall of the second division of the housing 1 a helical protruding rib 16 is provided defining an inner thread with a high pitch. A dose scale drum 17 is in its outer wall provided with a helical grove defining a corresponding external thread mating the inner thread just mentioned. The pitch angle of the threads exceeds the angle of friction for the materials forming the parts of the thread connection and consequently the thread connection is of the not self locking type which induce a relative rotation of the parts of the connection when these part are moved axially relative to each other.

Numbers indicating set doses are printed on the outer wall of the dose drum 17 and the number corresponding to a set dose is shown in a window 18 provided in the side wall of the housing 1.

The dose scale drum 17 is provide with a tubular extension 21 having an end near the proximal end of the syringe. Said end of the extension is closed by an end wall 19 having a central outer protrusion 20. In a part of the wall adjacent to the end wall 19 the extension 21 is provided with slots 22. The said end of the extension is covered by a cup shaped cap 23 forming an injection button. Internal hooks 24 at the open end of this cap snaps over an external circumferential bead 25 on the extension 21 and the protrusion 20 on the end wall 19 abuts the inner side of the bottom of the cap 23 to form a journal about which the injection button can rotate relative to the extension 21 whereas it cannot be axially displaced relative to this extension.

A driver tube 26 integral with the piston rod guide 14 extends from this piston rod guide to the end wall 19 of the dose scale drum extension 21 and is at its proximal end divided into tongues 27 terminated by external hooks 28 engaging the slots 22 in the extension 21. This way the dose scale drum 17 is bound to rotate with the driver tube 26 but is axially displaceable relative to this tube.

To set a dose the ampoule holder 2 is rotated anticlockwise in the first division of the housing 1. This rotation is performed against a resistance presented due to the fact that a protrusion 30 on the outer wall of the ampoule holder rests in one of a number of depressions 31 circumferentially provided in the inner wall of said first division of the housing as shown in the cross-sectional view in figure 3. The angular spacing of the depressions are appropriately made so that a dose of one unit is set when the protrusion is moved from one depression to the neighbouring depression so that the number of clicks heard and felt during the dose setting rotation corresponds to the size of the set dose.

The rotation of the ampoule holder is due to the friction in the engaging threads 5 and 7 transmitted to the piston rod 6 and further through the unidirectional coupling to the piston rod guide 14 although the torque is transmitted in a such a direction that the pawl will intend to click over the pawl wheel teeth 10. However, before this click function is performed a re-

luctance have to be overcome. This reluctance is obtained by providing the pawl 13 with a protrusion 29 at its end engaging the pawl wheel teeth 10 and by providing depressions 32 in the ramp shaped edges 12 of the pawl wheel teeth into which depressions the protrusion 29 on the pawl 13 will rest. Before the clicking release of the coupling is obtained a torque sufficient to lift up the protrusion 29 of the pawl 13 from the depression 32 in the ramp shaped edge 12 must be provided. Altogether a moderate torque can be transmitted from the rotated ampoule holder 2 to the driver tube 26. As the hooks 28 at the proximal end of the driver tube 26 engage the slots 22 in the dose scale drum extension 21 the dose scale drum will be rotated and be screwed upwards in the second division of the housing 1 and the injection button 23 will be lifted to protrude from the proximal end of the housing 1. As only a small torque is needed to screw up the dose scale drum this is obtained without releasing the unidirectional coupling to its clicking release function mode. The size of the set dose can currently be seen on the part of the dose scale drum which is presented in the window 18. If a too large dose has been set the ampoule holder can be rotated in a clockwise direction until the number corresponding to the size of the wanted doe is presented in the window 18.

To inject the set dose the injection button 23 is pressed home into the housing 1. Thereby the dose scale drum 17 is pressed in the distal direction and due to the thread connection between said drum and the housing 1 a torque is exerted on the drum rotating this drum in a clockwise direction. Said torque is via the slots 22 in the drum extension 21 and the hooks 28 at the end of the driver tube 26 and this tube itself transmitted to the piston rod guide 14. The pawls 13 on the piston rod guide are allowed to rotate in the clockwise direction when the torque is strong enough to overcome the reluctance provided by the protrusions 29 on the pawls engaging the depressions 32 in the ramp shaped edges of the pawl wheel teeth. Such a strong torque is provided if only the inject button 23 is pressed hard enough. The piston rod guide 14 will now rotate clockwise with the unidirectional coupling working in its clicking released mode and the piston rod will be rotated clockwise too and will thereby be screwed through the wall 4 further into the ampoule accommodating compartment 8. The unidirectional coupling will never allow an anticlockwise rotation of the piston rod guide and the piston and this way it is ensured that the pressure foot 9 will never be drawn out of abutment with the piston in a not shown ampoule in the compartment 8.

In the shown embodiment the end wall 4 with its threaded bore forms a nut member relative to which the piston rod is rotated by the piston rod guide 14 and the driver tube 26. Embodiments may be imagined wherein the piston rod guide is provided in the wall 4 and a nut element is rotated by the driver tube and such embodiment will not be beyond the scope of the invention.

Another embodiment is described with reference to the figures 6-10. Elements corresponding to elements in the embodiment described with references to the figures 1-5 are is provided with the same reference numbers. Different from the embodiment in figure 1-5 is the fact that the injection button 23 and not the dose scale drum 17 is provided with an extension 33, and that the driver tube 26 is omitted. Further the injection button 23 is provided with a flange 32 which abuts the end of the housing when the injection button is pressed home. The extension 33 serves as a journal for the dose scale drum 17 which is free to rotate on this journal but bound to follow axial movements of the injection button 23 due to hooks 34 at the end of the extension 33. A longitudinal bore 35 in the injection button and its extension 33 is provided with an internal helical rib 36 engaging a corresponding helical groove in an enlargement 37 at the proximal end of the piston rod to form a thread connection between said button 23 and said piston rod 6. The pitch of this thread connection is so that a not self locking thread connection is formed.

To set a dose the injection button 23 is manually rotated in a clockwise direction Thereby this button is screwed outwards from the housing 1 as the piston rod 6 will through the piston rod guide 14 and the unidirectional coupling be kept inrotatable although said unidirectional coupling in influenced by a torque in its release direction, however, due to the provided initial reluctance the piston rod guide 14 will not immediately be rotatable. In its movement outwards the injection button 23 will draw the dose scale drum 17 with it. When this drum is moved axially in the housing it will be rotated due to the not self locking thread connection between said drum 17 and the housing 1.

By this construction the thread along which the injection button is screwed outwards and the tread along which the dose scale drum is rotated in the housing may be different.
A click connection corresponding to the one established between the cartridge holder 2 and the housing 1 in the embodiment according to figure 1 is in the embodiment according to fig-

ure 6 appropriately provided between the injection button 23 and the housing 1 where one or more protrusions 38 provided on the inner wall of the housing engages grooves 39in a cylindrical outer wall of thebutton 23. Thereby axial movement of the injection button is allowed in all its possible angular positions.

When the injection button is pressed to inject a set dose said button will be maintained inrotatable during its axial movement as the locking between the above mentioned protrusions on the inner wall of the housing and grooves on the outer wall of the button is strong enough to absorb the torque exerted on the injection button when it drives the piston rod to rotation in a clockwise direction after having overcome the reluctance against rotation in the release direction of the unidirectional coupling.

CLAIMS

1. An injection syringes for apportioning set doses of a medicine from a cartridge containing an amount of medicine sufficient for the preparation of a number of therapeutic doses, comprising

a housing

a piston rod having a not circular cross-section and an outer thread

a piston rod drive comprising two elements

a) a piston rod guide in relation to which the piston rod is axially displaceable but not rotatable, and

b) a nut member which is rotatable but not axially displaceable in the housing and which has an inner thread mating the thread of the piston rod to form a self locking thread connection,

a dose setting mechanism comprising a not self locking thread connection along which an injection button by rotation of a dose setting element relative to said housing is screwed out from the proximal end of the housing to project from this proximal end a distance determined by the angle of said rotation and which thread connection by axial returning of the injection button transforms this axial movement to a rotation of one of the piston drive elements relative to the other,

characterised in that

a unidirectional coupling is provided between the nut member and the piston rod guide allowing rotation of these parts relative to each other in one direction but not in the opposite direction, the allowed rotation being one by which the piston rod is transported in a distal direction in the syringe, the coupling being so designed that a set initial reluctance has to be overcome before the rotation takes place.

2. An injection syringe according to claim 1, characterised in that a click coupling providing an moderate resistance against rotation in either directions is established between the housing and the element rotated relative to this housing to set a dose.

3. An injection syringe according to claim 1 or 2, characterised in that the unidirectional coupling comprises a pawl sliding over a pawl wheel with teeth having a steep front edge and a ramp shaped trailing edge.

4. An injection syringe according to claim 3, characterised in that the trailing edges of the pawl wheel teeth has a depression engaged by a mating protrusion on the pawl.

5. An injection syringe according to anyone of the preceding claims, characterised in that a dose scale drum has in its surface a helical track engaged by a helical rib on the inner side of the housing to form a not self locking thread connection between the housing and the drum and is coupled to the injection button to be moved axially with this button.

6. An injection syringe according to claim 5, characterised in that the thread connection by which the injection button is lifted by setting a dose is the thread connection between the dose scale drum and the housing.

7. An injection syringe according to claim 6, characterised in that the element rotated relative to the housing is a part carrying the nut member and the unidirectional coupling through which the rotation is transmitted to the dose setting drum.

8. An injection syringe according to claim 1, 2, 3, or 4 characterised in that the element rotated relative to the housing is the injection button and that the not self locking thread connection which determines the lifting of the injection button is an inner thread in a bore in the injection button engaging an outer thread on a part with enlarged diameter of the piston rod.

9. An injection syringe according to claim 8, characterised in that the dose scale drum is mounted rotatable but not axially displaceable on the injection button.

10. An injection syringe according to claim 8 or 9 characterised in that a click coupling between the housing and the injection button comprises protrusions on one part, the button or the housing, engaging axial grooves in the other to keep the button not rotatable but axially displaceable in all its angular positions defined by the click coupling.

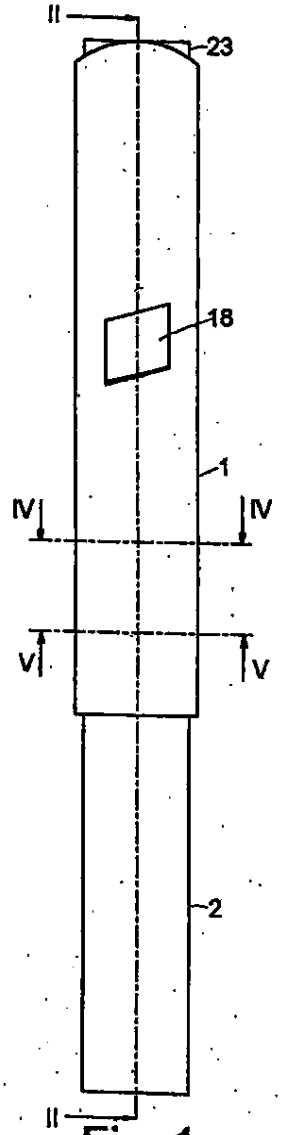

Fig. 1

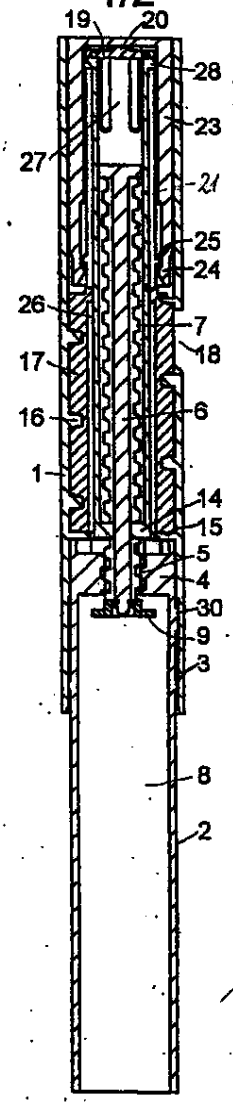

Fig.2

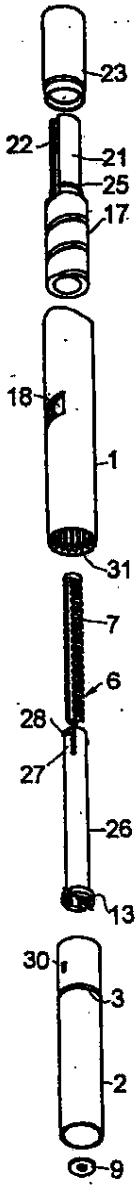

Fig.3

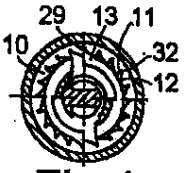

Fig.4

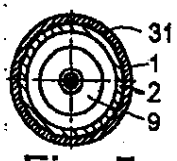

Fig. 5

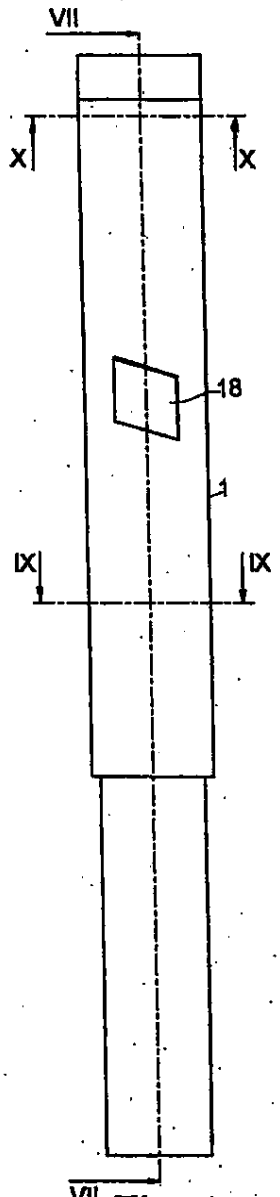

Fig. 6

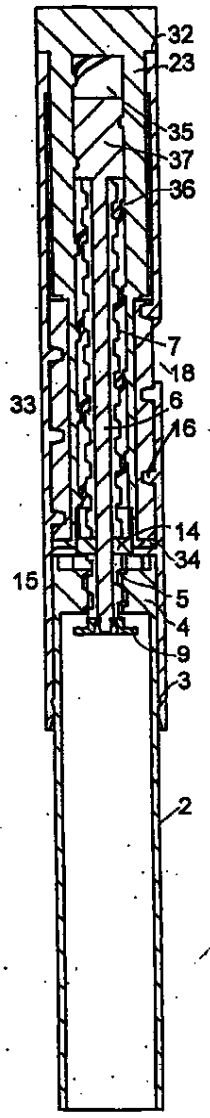

Fig. 7

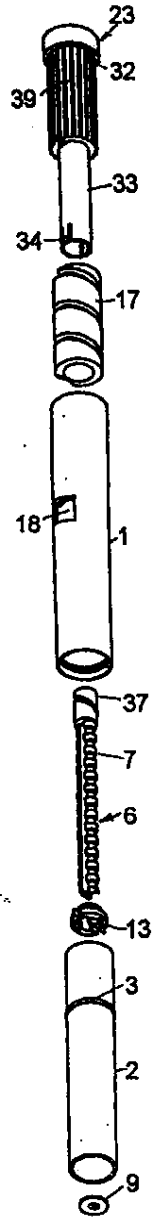

Fig.8

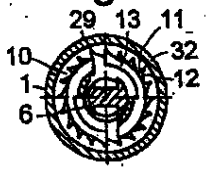

Fig. 9

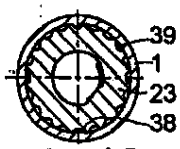

Fig.10

UNITED STAT DEPARTMENT OF COMMERCE
Patent and Trademark Office
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Washington, D.C. 20231

238849

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
09/238,849	01/28/99	STEENFELDT-JENSEN	S 5472.200-US

EXAMINER

QM31/0607

STEVE T ZELSON
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405 LEXINGTON AVE
SUITE 6400
NEW YORK NY 10174-6401

YASKO JR, T

ART UNIT	PAPER NUMBER
3763	4

DATE MAILED: 06/07/99

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☐ Responsive to communication(s) filed on _____

☐ This action is FINAL.

☒ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire Two month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-8 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☒ Claim(s) 1-8 is/are allowed.
☐ Claim(s) _____ is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☒ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

U.S. GPO: 1998-404-498/40617

SAN00828055

This application is in condition for allowance except for the following formal matters:

An Abstract of the Disclosure is required, 37 CFR 1.72 (b).

Prosecution on the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

A shortened statutory period for reply to this action is set to expire **TWO MONTHS** from the mailing date of this letter.

John Yasko:bhw
(703) 308-0858

May 26, 1999

JOHN D. YASKO
PRIMARY EXAMINER
3763

TO SEPARATE, HOLD TOP AND BOTTOM EDGES, SNAP–APART AN.

FORM PTO-892 (REV. 2-92) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

NOTICE OF REFERENCES CITED

SERIAL NO.	GROUP ART UNIT	ATTACHMENT TO PAPER NUMBER
238849	3763	4

APPLICANT(S): STEENFELDT-JENSEN et al

U.S. PATENT DOCUMENTS

*		DOCUMENT NO.	DATE	NAME	CLASS	SUB-CLASS	FILING DATE IF APPROPRIATE
X	A	5017190	5-91	SIMON et al	604	207	
X	B	5304152	4-94	SAMS	604	207	
X	C	5674204	10-97	CHANOCH	604	211	
X	D	5679111	10-97	HJERTMAN et al	604	208x	
X	E	5599314	2-97	NEILL	604	207	
X	F	5725508	3-98	SAMS	604	232x	
	G						
	H						
	I						
	J						
	K						

FOREIGN PATENT DOCUMENTS

*		DOCUMENT NO.	DATE	COUNTRY	NAME	CLASS	SUB-CLASS	PERTINENT SHTS. DWG	PERTINENT PP. SPEC.
	L								
	M								
	N								
	O								
	P								
	Q								

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

	R	
	S	
	T	
	U	

EXAMINER	DATE
J. YASKO	5-26-99

* A copy of this reference is not being furnished with this office action.
(See Manual of Patent Examining Procedure, section 707.05 (a).)

PATENT

Attorney Docket No.: 5472.200-US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#5/Response to missing parts w/Decl.

In re Application of: Steenfeldt-Jensen et al.

Serial No.: 09/238,849 Group Art Unit: To be assigned

Filed: January 28, 1999 Examiner: To be assigned

For: An Injection Syringe

RESPONSE TO NOTICE TO FILE MISSING PARTS

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

Applicants submit the Combined Declaration and Power of Attorney signed and dated by Applicants for the above-captioned application. Applicants never received a Notice To File Missing Parts, therefore we are submitting the attached executed Declaration.

Please charge the required fee, estimated to be $130.00, to Novo Nordisk of North America, Inc., Deposit Account No. 14-1447. Please credit any overpayment to Deposit Account No. 14-1447. A duplicate of this sheet is enclosed.

Respectfully submitted,

Valeta A. Gregg

Date: June 16, 1999

Valeta A. Gregg, Reg. No. 35,127
Novo Nordisk of North America, Inc.
405 Lexington Avenue, Suite 6400
New York, NY 10174-6401
(212) 867-0123

3701

Sector 7

Attorney Docket No.: 5472.200-US PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Steenfeldt-Jensen et al.

Serial No.: 09/238,849 Group Art Unit: To be assigned

Filed: January 28, 1999 Examiner: To be assigned

For: An Injection Syringe

CERTIFICATE OF MAILING UNDER 37 CFR 1.8(a)

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

I hereby certify that the attached correspondence comprising:

1. Executed Combined Declaration and Power of Attorney

is being deposited with the United States Postal Service as first class mail in an envelope addressed to:

Commissioner of Patents and Trademarks
Washington, DC 20231

on June 16, 1999.

Ann Quintero
(name of person mailing paper)

Ann Quintero
(signature of person mailing paper)

COMBINED DECLARATION FOR P NT APPLICATION AND POWER OF ATTOR (Includes Reference to PCT International Applications).	Attorney's Docket Number 4472.200-US

JUN 21 1999 PATENT & TRADEMARK OFFICE

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

An Injection Syringe

the specification of which (check only one item below):

[ ] is attached hereto

[X] was filed as United States application

Application No. to be assigned

on January 28, 1999

and was amended

on

[ ] was filed as PCT international application

Number

on

and was amended under PCT Article 19

on

RECEIVED JUL 07 1999 Group 3700

RECEIVED JUL 01 1999 TECHNOLOGY CENTER 3700

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability of this application in accordance with Title 37, Code of Federal Regulations, §1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign applications(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign applications(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed:

PRIOR FOREIGN/PCT APPLICATION(S) AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. 119:

COUNTRY (if PCT, indicate "PCT")	APPLICATION NUMBER	DATE OF FILING (day, month, year)	PRIORITY CLAIMED UNDER 35 USC 119
DK	PA 1998 00130	30 January 1998	[x] YES [ ] NO
US	60/073,820	5 February 1998	[x] YES [ ] NO
			[ ] YES [ ] NO
			[ ] YES [ ] NO
			[ ] YES [ ] NO
			[ ] YES [ ] NO

COMBINED DECLARATION FOR P NT APPLICATION AND POWER OF ATTOR (Includes Reference to PCT nternational Applications)

Attorney's Docket Number: 5472.200-US

I hereby claim the benefit under Title 35, United States Code §120 of any United States application(s) or PCT international application(s) designating the United States of America that is/are listed below and, insofar as the subject matter of each of the claims of this applications is not disclosed in that/those prior application(s) in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application(s) and the national or PCT international filing date of this application:

PRIOR U.S. APPLICATIONS OR PCT INTERNATIONAL APPLICATIONS DESIGNATING THE U.S. FOR BENEFIT UNDER 35 U.S.C. 120:

U.S. APPLICATIONS		STATUS (Check one)		
U.S. APPLICATION NUMBER	U.S. FILING DATE	Patented	Pending	Abandoned

RECEIVED
JUL U 1 1999
TECHNOLOGY CENTER 3700

PCT APPLICATIONS DESIGNATING THE U.S.					
APPLICATION NO.	FILING DATE	US SERIAL NUMBER ASSIGNED (if any)			

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

Steve T. Zelson Reg. No. 30,335 | Elias J. Lambiris Reg. No. 33,728 | Valeta A. Gregg Reg. No. 35,127 | Carol E. Rosek Reg. No. 36,993 | Robert L. Starnes Reg. No. 41,324 | Reza Green Reg. No. 38,475

Send Correspondence to: Steve T. Zelson, Esq.
Novo Nordisk of North America, Inc.
405 Lexington Avenue, Suite 6400
New York, New York 10174-6401

Direct Telephone Calls To: Steve T. Zelson (212) 867-0123

		Family Name	First Given Name	Second Given Name
1	Full Name of Inventor	Steenfeldt-Jensen	Søren	
	Residence & Citizenship	City: Hornbæk	State or Foreign Country: Denmark	Country of Citizenship: Denmark
	Post Office Address	Post Office Address: Holmevænget 2B	City: DK-3100 Hornbæk	State & Zip Code/Country: Denmark
2	Full Name of Inventor	Hansen	Steffen	
	Residence & Citizenship	City: Hillerød	State or Foreign Country: Denmark	Country of Citizenship: Denmark
	Post Office Address	Post Office Address: Gl. Frederiksborgvej 64A	City: DK-3400 Hillerød	State & Zip Code/Country: Denmark
3	Full Name of Inventor	Family Name:	First Given Name:	Second Given Name:
	Residence & Citizenship	City:	State or Foreign Country:	Country of Citizenship:
	Post Office Address	Post Office Address:	City:	State & Zip Code/Country:

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Signature of Inventor 1	Signature of Inventor 2	Signature of Inventor 3
S. Steenfeldt-J		
Date 9/2 - 1999	Date 9/2-1999 Steffen H	Date

Docket No. 5472.200-US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	Steenfeldt-Jensen et al.	
Serial No.	:	09/238,849	Examiner: Yasko, Jr., J.
Filed	:	January 28, 1999	Art Unit: 3763
Title	:	An Injection Syringe	

I hereby certify that this paper is being deposited with the United States Postal Service, as first class mail, in an envelope addressed to: Assistant Commissioner for Patents, Washington, DC 20231, on July 23, 1999.

Robert B. Smith — Reg. No. 28,538

Robert B. Smith — July 23, 1999

Signature — Date

July 23, 1999

AMENDMENT

Assistant Commissioner For Patents
Washington, DC 20231

Sir:

In response to the Office Action dated June 7, 1999, please amend the above-identified application as follows:

Please add the attached Abstract of the Disclosure

IN THE CLAIMS

On page 19, line 3, change "An injection syringes" to - - 1. An injection syringe - -;

line 7, after "a housing" insert a semicolon; and

line 11, after "two elements" insert a colon.

REMARKS

The applicants thank the Examiner for the indication that the application is in condition for allowance except for the lack of an Abstract of the Disclosure. An Abstract was submitted as a separate page (page 21) of the original application which evidently may have been separated from the file. Rather than re-submitting a copy of page 21, attached hereto is a new Abstract which is substantively the same, but in which certain grammatical revisions have been made.

Favorable consideration and allowance of the application are respectfully requested.

Respectfully submitted,

Robert B. Smith
PTO Registration No. 28,538
Attorney for applicant(s)
(212) 819-8547

GAU 3763

WHITE & CASE
1155 Avenue of the Americas
New York, NY 10036-2787

Telephone: (212) 819-8200
Facsimile: (212) 354-8113

Date: July 23, 1999
File No. 5472200-US

Applicant	:	Steenfeldt-Jensen et al.
Serial No.	:	09/238,849
Filed	:	January 28, 1999
Title	:	An Injection Syringe

Examiner: Yasko, Jr., J.

Art Unit: 3763

AMENDMENT TRANSMITTAL
AND CONDITIONAL REQUEST FOR EXTENSION OF TIME

Assistant Commissioner For Patents
Washington, DC 20231

Sir:

I hereby certify that this paper is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, DC 20231, on

July 23, 1999
Date of Deposit

Robert B. Smith — Attorney Name
28,538 — Registration No.

Robert B. Smith — Signature
July 23, 1999 — Date of Signature

Docket No. 5472.200-US

Transmitted herewith is an Amendment in the above-identified application.

1. ( ) No additional fee is required.

2. ( ) The fee has been calculated as shown below:

Claims remaining		Prior Paid Claims		Extra		Rate		Fee
Total:	minus	(at least 20)	=		@	$22	=	$
Independent	minus	(at least 3)	=		@	$82	=	$____

TOTAL ADDITIONAL FEE: $

3. ( ) An extension of time to respond to the PTO Communication dated June 7, 1998 is hereby requested. The required fee is indicated below:

Within first month:	( )	$110
Within second month	( )	$380
Within third month	( )	$870
Within fourth month	( )	$1,360
Within the fifth month	( )	$1,850

4. ( ) Enclosed please find a check in the amount of $ 0.00 representing (a) additional claims fee ($ 0) and (b) the extension fee ($ 0).

5. ( ) The Commissioner is hereby authorized to charge the amount of $ 0 representing (a) additional claims fee ($ 0) and (b) the extension fee ($ 0) to deposit account No. 23-1703. A copy of this sheet is enclosed for such purpose.

6. (X) In the event that an extension of time is required and applicant has inadvertently overlooked the need to request a petition and file the fee, the applicant hereby petitions for such extension of time. The Commissioner is authorized to charge the required fee to deposit account No. 23-1703. A copy of this sheet is enclosed for such purpose.

Docket No. 5472.200-US

7. (X) The Commissioner is hereby authorized to charge payment of any additional fees required in connection with this application, and credit any overpayment, to deposit account No. 23-1703. A copy of this sheet is enclosed.

WHITE & CASE

By Robert B. Smith

Robert B. Smith
Registration No. 28,538
Attorneys for Applicant(s)
(212) 819-8547
smithro@newyork.whitecase.com

Docket No. 5472.200-US

09/-238,849

ABSTRACT OF THE DISCLOSURE

An injection syringe comprises a housing (1), a piston rod (6) with a non-circular cross-section and an outer thread (7), a piston rod drive which includes a piston rod guide (85) mating with the cross-section of the piston rod (6), and a nut (4) which is not axially displaceable and which mates with the thread (7) of the piston rod (6) to form a self-locking thread connection. Rotation of a dose setting element (81) causes an injection button to be screwed out to project from the housing (1). When the injection button (88) is pushed axially, such axial movement is transformed, by way of the threaded coupling, into a rotation of one of the piston drive elements (85) relative to the other one (4). A unidirectional coupling between the nut member (4) and the piston rod guide (85) allows rotation in one direction by which the piston rod (6) is transported in a distal direction. The coupling has an initial reluctance to be overcome before rotation takes place, said reluctance being large enough to resist torques exerted during the dose setting.

WHITE & CASE
1155 Avenue of the Americas
New York, NY 10036-2787

Telephone: (212) 819-8200
Facsimile: (212) 354-8113

Date: July 23, 1999
File No. 5472.200-US

Applicant	:	Steenfeldt-Jensen et al.
Serial No.	:	09/238,849
Filed	:	January 28, 1999
Title	:	An Injection Syringe

Examiner: Yasko, Jr., J.

Art Unit: 3763

AMENDMENT TRANSMITTAL
AND CONDITIONAL REQUEST FOR EXTENSION OF TIME

Assistant Commissioner For Patents
Washington, DC 20231

Sir:

I hereby certify that this paper is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, DC 20231, on

July 23, 1999.
Date of Deposit

Robert B. Smith
Attorney Name

28,538
Registration No.

Robert B. Smith
Signature

July 23, 1999
Date of Signature

Docket No. 5472.200-US

Transmitted herewith is an Amendment in the above-identified application.

1. ( ) No additional fee is required.

2. ( ) The fee has been calculated as shown below:

Claims remaining		Prior Paid Claims		Extra		Rate		Fee
Total:	minus	(at least 20)	=		@	$22	=	$
Independent	minus	(at least 3)	=		@	$82	=	$
				TOTAL ADDITIONAL FEE:				$

3. ( ) An extension of time to respond to the PTO Communication dated June 7, 1998 is hereby requested. The required fee is indicated below:

Within first month:	( )	$110
Within second month	( )	$380
Within third month	( )	$870
Within fourth month	( )	$1,360
Within the fifth month	( )	$1,850

4. ( ) Enclosed please find a check in the amount of $ 0.00 representing (a) additional claims fee ($ 0) and (b) the extension fee ($ 0).

5. ( ) The Commissioner is hereby authorized to charge the amount of $ 0 representing (a) additional claims fee ($ 0) and (b) the extension fee ($ 0) to deposit account No. 23-1703. A copy of this sheet is enclosed for such purpose.

6. (X) In the event that an extension of time is required and applicant has inadvertently overlooked the need to request a petition and file the fee, the applicant hereby petitions for such extension of time. The Commissioner is authorized to charge the required fee to deposit account No. 23-1703. A copy of this sheet is enclosed for such purpose.

7. (X) The Commissioner is hereby authorized to charge payment of any additional fees required in connection with this application, and credit any overpayment, to deposit account No. 23-1703. A copy of this sheet is enclosed.

WHITE & CASE

By Robert B. Smith

Robert B. Smith
Registration No. 28,538
Attorneys for Applicant(s)
(212) 819-8547
smithro@newyork.whitecase.com

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
238849 ~~09/238,849~~	~~01/28/99~~	STEENFELDT-JENSEN	5472.201-US

QM12/0805

STEVE T ZELSON
NOVO NORDISK OF NORTH AMER INC
405 LEXINGTON AVE
SUITE 6400
NEW YORK NY 10174-6401

EXAMINER	
YASKO JR, J	
ART UNIT	**PAPER NUMBER**
3763	7

DATE MAILED: 08/05/99

NOTICE OF ALLOWABILITY

PART I.

1. ☒ This communication is responsive to JULY 26, 1999.
2. ☒ All the claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice Of Allowance And Issue Fee Due or other appropriate communication will be sent in due course.
3. ☒ The allowed claims are 1-8.
4. ☒ The drawings filed on 1-28-99 are acceptable.
5. ☐ Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy has [_] been received. [_] not been received. [_] been filed in parent application Serial No. _____, filed on _____.
6. ☐ Note the attached Examiner's Amendment.
7. ☐ Note the attached Examiner Interview Summary Record, PTOL-413.
8. ☐ Note the attached Examiner's Statement of Reasons for Allowance.
9. ☐ Note the attached NOTICE OF REFERENCES CITED, PTO-892.
10. ☐ Note the attached INFORMATION DISCLOSURE CITATION, PTO-1449.

PART II.

A SHORTENED STATUTORY PERIOD FOR RESPONSE to comply with the requirements noted below is set to EXPIRE THREE MONTHS FROM THE "DATE MAILED" indicated on this form. Failure to timely comply will result in the ABANDONMENT of this application. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

1. ☐ Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL APPLICATION, PTO-152, which discloses that the oath or declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED.
2. ☐ APPLICANT MUST MAKE THE DRAWING CHANGES INDICATED BELOW IN THE MANNER SET FORTH ON THE REVERSE SIDE OF THIS PAPER.
   a. ☐ Drawing informalities are indicated on the NOTICE RE PATENT DRAWINGS, PTO-948, attached hereto or to Paper No. _____. CORRECTION IS REQUIRED.
   b. ☐ The proposed drawing correction filed on _____ has been approved by the examiner. CORRECTION IS REQUIRED.
   c. ☐ Approved drawing corrections are described by the examiner in the attached EXAMINER'S AMENDMENT. CORRECTION IS REQUIRED.
   d. ☐ Formal drawings are now REQUIRED.

Any response to this letter should include in the upper right hand corner, the following information from the NOTICE OF ALLOWANCE AND ISSUE FEE DUE: ISSUE BATCH NUMBER, DATE OF THE NOTICE OF ALLOWANCE, AND SERIAL NUMBER.

Attachments:

- _ Examiner's Amendment
- _ Examiner Interview Summary Record, PTOL-413
- _ Reasons for Allowance
- _ Notice of References Cited, PTO-892
- _ Information Disclosure Citation, PTO-1449
- _ Notice of Informal Application, PTO-152
- _ Notice re Patent Drawings, PTO-948
- _ Listing of Bonded Draftsmen
- _ Other

J. Yasko
PRIMARY EXAMINER
ART UNIT 3763

PTOL-37 (REV. 4-96) *

USCOMM-DC 80-3700

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

NOTICE OF ALLOWANCE AND ISSUE FEE DUE

QM12/0805

STEVE T ZELSON
NOVO NORDISK OF NORTH AMER INC
405 LEXINGTON AVE
SUITE 6400
NEW YORK NY 10174-6401

APPLICATION NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED
09/238,649	01/28/99	008	YASKO JR, J	3763 08/05/99

First Named Applicant	35 USC 154(b) term ext. =
STEENFELDT-JENSEN,	0 Days.

TITLE OF INVENTION: INJECTION SYRINGE

ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
3 5472.200-US	604-207.000	W78	UTILITY	NO	$1210.00	11/05/99

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED.

THE ISSUE FEE MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED.

HOW TO RESPOND TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is changed, pay twice the amount of the FEE DUE shown above and notify the Patent and Trademark Office of the change in status, or
B. If the status is the same, pay the FEE DUE shown above.

If the SMALL ENTITY is shown as NO:

A. Pay FEE DUE shown above, or

B. File verified statement of Small Entity Status before, or with, payment of 1/2 the FEE DUE shown above.

II. Part B-Issue Fee Transmittal should be completed and returned to the Patent and Trademark Office (PTO) with your ISSUE FEE. Even if the ISSUE FEE has already been paid by charge to deposit account, Part B Issue Fee Transmittal should be completed and returned. If you are charging the ISSUE FEE to your deposit account, section "4b" of Part B-Issue Fee Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give application number and batch number. Please direct all communications prior to issuance to Box ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PATENT AND TRADEMARK OFFICE COPY

PTOL-85 (REV. 10-96) Approved for use through 06/30/99. (0651-0033)

*U.S. GPO: 1996-437-639/60023

PART B—ISSUE FEE TRANSMITT

Complete and mail this form, together with applicable fees, to: **Box ISSUE FEE**
Assistant Commissioner for Patents
Washington, D.C. 20231

AUG 3 0 1999

MAILING INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE. Blocks 1 through 4 should be completed where appropriate. All further correspondence including the Issue Fee Receipt, the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Legibly mark-up with any corrections or use Block 1)

GM12/0805
STEVE T ZELSON
NOVO NORDISK OF NORTH AMER INC
405 LEXINGTON AVE
SUITE 6400
NEW YORK NY 10174-6401

Note: The certificate of mailing below can only be used for domestic mailings of the Issue Fee Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing.

Certificate of Mailing

I hereby certify that this Issue Fee Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Box Issue Fee address above on the date indicated below.

GINA MALDONADO (Depositor's name)
(Signature)
8/17/99 (Date)

APPLICATION NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT		DATE MAILED
09/238,849	01/28/99	008	YASKO JR, J	3763	08/05/99

First Named Applicant: STEENFELDT-JENSEN, 35 USC 154(b) term ext. = 0 Days.

TITLE OF INVENTION: INJECTION SYRINGE

ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
3 5472.200-US	604-207.000	W78	UTILITY	NO	$1210.00	11/05/99

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363). Use of PTO form(s) and Customer Number are recommended, but not required.
☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
☐ "Fee Address" Indication (or "Fee Address" Indication form PTO/SB/47) attached.

2. For printing on the patent front page, list (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.
1 Steve T. Zelson, Esq.
2
3

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)
PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. Inclusion of assignee data is only appropriate when an assignment has been previously submitted to the PTO or is being submitted under separate cover. Completion of this form is NOT a substitute for filing an assignment.
(A) NAME OF ASSIGNEE Novo Nordisk A/S
(B) RESIDENCE: (CITY & STATE OR COUNTRY) Novo Allé, DK-2880 Bagsværd, Denmark
Please check the appropriate assignee category indicated below (will not be printed on the patent)
☐ Individual ☑ Corporation or other private group entity ☐ Government

4a. The following fees are enclosed (make check payable to Commissioner of Patents and Trademarks):
☐ Issue Fee
☐ Advance Order - # of Copies

4b. The following fees or deficiency in these fees should be charged to:
DEPOSIT ACCOUNT NUMBER 14-1447
(ENCLOSE AN EXTRA COPY OF THIS FORM)
☑ Issue Fee
☑ Advance Order - # of Copies 6

The COMMISSIONER OF PATENTS AND TRADEMARKS is requested to apply the Issue Fee to the application identified above.

(Authorized Signature) Steve T. Zelson (Date) 8/17/99

NOTE: The Issue Fee will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the Patent and Trademark Office.

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending on the needs of the individual case. Any comments on the amount of time required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND FEES AND THIS FORM TO: Box Issue Fee, Assistant Commissioner for Patents, Washington D.C. 20231

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

08/26/1999 TLUBER 00000151 141447
01 FC:142 1210.00 CH
02 FC:561 10.00 CH

TRANSMIT THIS FORM WITH FEE

PTOL-85B (REV.10-96) Approved for use through 06/30/99: OMB 0651-0033 Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

SAN00828073

S.L. 11-23-99

Attorney Docket No.: 5472.200-US PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#8/EDS

In re Application of: Steenfeldt-Jensen et al.

Serial No.: 09/238,849 Group Art Unit: 3763

Filed: January 28, 1999 Examiner: Yasko, Jr., J.

For: An Injection Syringe

CERTIFICATION ON FILING INFORMATION
DISCLOSURE STATEMENT UNDER 37 CFR 1.97(e)

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

I hereby certify that each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the statement.

Respectfully submitted,

Date: August 10, 1999

Reza Green, Reg. No. 38,475
Novo Nordisk of North America, Inc.
405 Lexington Avenue, Suite 6400
New York, NY 10174-6401
(212) 867-0123

Attorney Docket No.: 5472.200-US PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Steenfeldt-Jensen et al.

Serial No.: 09/238,849 Group Art Unit: 3763

Filed: January 28, 1999 Examiner: Yasko, Jr., J.

For: An Injection Syringe

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

In accordance with 37 C.F.R. 1.56, 1.97 and 1.98, Applicants submit references which they believe may be material to the patentability of this application and with respect to which there may be a duty to disclose in accordance with 37 C.F.R. 1.56.

While the references may be "material" under 37 C.F.R. 1.56, it is not intended to constitute an admission that the references are "prior art" unless specifically designated as such.

The filing of this Information Disclosure Statement shall not be construed as a representation that no other material references than those listed exist or that a search has been conducted.

The references are listed in PTO form 1449 which is in accordance with the requirements of M.P.E.P. 609. A copy of the references is also enclosed.

The references are as follows:

1. US Patent No. 5,674,204
2. WO 93/07922
3. EP 0 327 910 A2
4. EP 0 450 905 A1

It is respectfully requested that these references be considered by the Patent and Trademark Office in its examination of the above-identified application and be made of record therein. The Examiner is also invited to contact the Undersigned if there are any questions concerning this paper or the attached references.

Respectfully submitted,

Date: August 10, 1999

Reza Green, Reg. No. 38,475
Novo Nordisk of North America, Inc.
405 Lexington Avenue, Suite 6400
New York, NY 10174-6401
(212) 867-0123

Sheet 1 of 1

FORM PTO-1449 (Rev. 2-32)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	Atty. Docket No. 5472.200-US	Serial No. 09/238,849
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Applicant Steenfeldt-Jensen et al.	
(Use several sheets if necessary)		Filing Date January 28, 1999	Group 3763

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
JW		5,674,204	10/7/97	Chanoch			

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	TRANSLATION NO
JW		WO 93/07922	4/29/93	PCT				
		EP 0 327 910	8/16/89	Europe				
		EP 0 450 905	10/9/91	Europe				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

EXAMINER	JOHN D. YASKO JW	DATE CONSIDERED	11-23-99

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Gp 3763

Attorney Docket No.: 5472.200-US PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Steenfeldt-Jensen et al.

Serial No.: 09/238,849 Group Art Unit: 3763

Filed: January 28, 1999 Examiner: Yasko, Jr., J.

For: An Injection Syringe

CERTIFICATE OF MAILING UNDER 37 CFR 1.8(a)

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

I hereby certify that the attached correspondence comprising:

1. Certification On Filing Information Disclosure Statement Under 37 CFR 1.97(e)
2. Information Disclosure Statement
3. PTO-1449 Form
4. Copy of References

is being deposited with the United States Postal Service as first class mail in an envelope addressed to:

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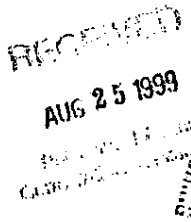
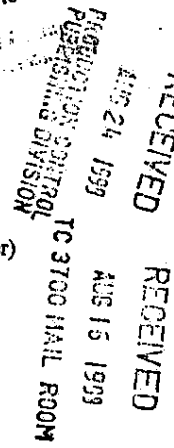
on August 10, 1999





Gina Maldonado
(name of person mailing paper)

(signature of person mailing paper)

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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
09/238,849	01/28/99	STEENFELDT-JENSEN	5472.280-US

QM31/1129

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EXAMINER	
YASKO JR, J	

ART UNIT	PAPER NUMBER
3763	9

DATE MAILED: 11/29/99

A. ☐ The petition filed _____ under 37 CFR 1.312(b) is granted.
The paper has been forwarded to the examiner for consideration on the merits.

B. ☒ The amendment filed AUG 12, 1999 under 37 CFR 1.312 has been considered, and has been:

1. ☒ entered COPY 1449 ATTACHED.
2. ☐ entered as directed to matters of form not affecting the scope of the invention (0.3311).
3. ☐ disapproved. A report appears below.
4. ☐ entered in part. A report appears below.

Report:

J. Yasko 3763

PLEASE FURNISH YOUR ZIP CODE IN ALL CORRESPONDENCE

FORM PTOL-271 (REV. 7/89)

SAN00828079